NATIONAL INSTITUTE FOR HEALTH AND CARE EXCELLENCE

EARLY VALUE ASSESSMENT PROGRAMME

Early value assessment guidance consultation document

Digital technologies for managing non-specific low back pain: early value assessment

Guidance development process

Early value assessment (EVA) guidance rapidly 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 more evidence is generated.

The medical technologies advisory committee has considered the evidence and the views of clinical and patient experts. 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.

More evidence will be generated over the next 3 years to assess if the benefits of these 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.

This document has been prepared for public consultation. It summarises the evidence and views that have been considered and sets out the recommendations made by the committee. NICE invites comments from registered stakeholders, healthcare professionals and the public. This document should be read along with the evidence (an EVA report and the EVA report addendum).

The advisory 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?

Equality issues

NICE is committed to promoting equality of opportunity, eliminating unlawful discrimination and fostering good relations between people with particular protected characteristics and others. Please let us know if you think that the recommendations may need changing to meet these aims. In particular, please tell us if the recommendations:

- could have a different effect on people protected by the equality legislation than on the wider population, for example by making it more difficult in practice for a specific group to access the technology
- could have any adverse effect on disabled people.

Please provide any relevant information or data you have about such effects and how they could be avoided or reduced.

Note that this document is not NICE's final guidance on digital technologies for managing non-specific low back pain. The recommendations in section 1 may change after consultation.

After consultation, NICE will consider the comments received. The final recommendations will be the basis for NICE's early value guidance.

Key dates:

Closing date for comments: 25 October 2023

1 Recommendations

Can be used in the NHS with evidence generation

1.1 Seven digital technologies can be used in the NHS while more evidence is generated to manage non-specific low back pain in people aged 16 and over. The technologies are:

- ACT for PAIN (company states CE mark or UKCA not required)
- getUBetter (company states CE mark or UKCA in place)
- Hinge Health (company states in process of getting regulatory approval)
- Kaia (regulatory status unknown)
- Pathway through Pain (company states CE mark or UKCA in place)
- selfBACK (regulatory status unknown)
- SupportBack (regulatory status unknown).

These technologies can be used once they have appropriate regulatory approval and meet the standards within NHS England's Digital Technology Assessment Criteria (DTAC).

1.2 The companies must confirm that agreements are in place to generate the evidence (as outlined in NICE's evidence generations plan), and contact NICE annually to confirm that evidence is being generated and analysed as planned. NICE may withdraw the guidance for a technology if these conditions are not met.

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

Can only be used in research

1.4 More research is needed on Ascenti Reach and Phio Engage (regulatory status unknown for both technologies) to manage non-specific low back pain in people aged 16 and over.

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

Evidence generation and research

1.6 More evidence generation and research are needed on:

- pain and disability using the same outcome measure (Musculoskeletal Health Questionnaire)
- quality of life using the same outcome measure (EQ-5D-5L)
- patient characteristics (such as type of back pain and severity)
- time until return to normal activity
- treatment adherence, that is, the number of people:
  - using a technology at baseline, 30 days and between 6 months and 1 year
  - who stop using a technology and their reasons for stopping
- healthcare resource use, including:
  - GP appointments
  - physiotherapy appointments
  - emergency department visits
- how many people have self-referred for the technology and how many have been referred by a healthcare practitioner
- the position of the technology in the care pathway
- patients' views on the effects of the technologies collected using a qualitative survey or through interviews.

Potential benefits of use in the NHS with evidence generation

- **Access:** Digital technologies for managing non-specific low back pain provide access to rapid advice and offer another treatment option. They will particularly benefit anyone who needs more flexible access to treatment or prefers a digitally enabled therapy over face-to-face therapy.
- **Clinical benefit:** Clinical evidence suggests that digital technologies for managing non-specific low back pain may reduce pain and improve ability to function in everyday life.
- **Resources:** These technologies could potentially reduce waiting lists, referrals for physiotherapy and the number of physiotherapy appointments and GP visits, medication use and the need for surgery.

Considerations

- **Costs:** Early results from the economic modelling suggest that the technologies used alongside standard care may be cost effective compared with standard care alone. The potential cost effectiveness or cost saving will be affected by how they are used in the clinical pathway. This guidance will be reviewed within 3 years and the recommendations may change. Take this into account when negotiating the length of contracts and licence costs.
- **Information governance**: Local NHS hospitals and trusts should have appropriate information governance policies for using these technologies.
- **Patient outcomes:** Consistent quality-of-life measures should be used.
- **Equality:** Digitally enabled therapies may not be accessible to everyone. Adults with limited access to equipment or an internet connection, or who are less comfortable or skilled at using digital technologies, are less likely to benefit and may prefer another treatment option.

Key gaps in the evidence

- No clinical evidence was identified for Ascenti Reach, ACT for PAIN, Pathway through Pain or Phio Engage.
- It is difficult to compare technologies because a wide range of outcome measures were used. Also, some outcomes were not well-reported, such as work productivity, and patient experience and satisfaction.
- There was limited evidence on how they affect psychological management, quality of life, attendance at emergency departments, and referral rates to other services such as imaging, physiotherapy or surgery.

Overall, more evidence is needed on:

- the clinical effectiveness of digital technologies for low back pain
- technology uptake and rate of adherence
- healthcare resource use.

2 The technologies

2.1 Digital technologies for managing low back pain (LBP) could provide rapid access to specialist advice and guidance, remote pain management support including physical activity recommendations and psychological therapies through web-based applications and digital platforms. They could offer greater flexibility because people can work through the recommendations in their own time with varying levels of support. Digital technologies for managing LBP are not homogenous and have different focuses based on the characteristics of the person with LBP. For example, some technologies are designed for acute LBP, some for chronic LBP and some for a mixture of both.

2.2 NICE has assessed 9 digital technologies for managing non-specific LBP. The assessment included technologies that offer physical, psychological, or both types of management of LBP. The criteria for including technologies in this assessment are in the final scope on the NICE website. The included technologies are:

- ACT for PAIN (Pain Medicine Specialist Ltd)
- Ascenti Reach (Ascenti)
- getUBetter (getUBetter)
- Hinge Health (Hinge Health)
- Kaia (Kaia Health)
- Pathway through Pain (Wellmind Health)
- Phio Engage (EQL)
- selfBACK (SelfBack Consortium)
- SupportBack (University of Southampton).

See table 2.1 in the assessment report for details of the technologies.

Care pathway

2.3 The target population for this assessment is people aged 16 and over with non-specific LBP. The condition can either be acute (that is, lasting less than 3 months) or chronic (that is, lasting 3 months or more). NICE's guideline on low back pain and sciatica in over 16s recommends considering several non-pharmacological interventions for treating LBP. These include self-management, exercise, manual therapies, psychological therapies, combined physical and psychological programmes, and return to work programmes. It recommends that these interventions are tailored to someone's specific needs, preferences and capabilities.

2.4 Acceptance and commitment therapy (ACT) and cognitive behavioural therapy (CBT) delivered by healthcare professionals with appropriate

training are recommended in NICE's guideline on chronic pain (primary and secondary) in over 16s.

2.5 Digital technologies for managing LBP would be offered after clinical assessment and diagnosis, or through self-referral, as an addition to non-pharmacological treatment for LBP. Technologies eligible for self-referral will be those with integrated assessment and risk stratification. This is to ensure that red flags which may indicate a serious underlying cause are identified. Technologies that provide psychological support only may not be suitable for people with acute LBP because their pain has lasted less than 3 months.

The comparator

2.6 The comparator is standard care for managing non-specific LBP. Digital technologies would be used in addition to standard care. Standard care varies significantly across primary and community care.

3 Committee discussion

NICE's medical technologies advisory committee considered evidence on digital technologies to manage non-specific low back pain (LBP) in people aged 16 and over from several sources, including an early value assessment (EVA) report by the external assessment group (EAG) and an overview of that report. Full details are in the project documents for this guidance on the NICE website.

Unmet need

3.1 Provision of services for musculoskeletal-related pain varies across the NHS. Most non-specific LBP is managed in primary or community care settings, which has limited workforce capacity and resources to meet the growing demand for services. The clinical experts noted that there is often a long waiting list for referral to specialist services and that people are likely to try to resolve pain on their own before seeing the GP.

3.2 Digital technologies for managing non-specific LBP that are suitable for self-referral would provide people with the resource they need to self-manage. One clinical expert noted that there was no evidence about people who self-referred. But, in practice, healthcare professionals will want to use digital technologies to ease the strain on resource use.

Implementation

3.3 Some of the technologies included in this assessment are used in the NHS. The committee stated that technologies designed to interact with GP systems ensure continuity of care by making important information accessible to healthcare professionals that need it. The companies for ACT for PAIN, getUBetter, Hinge Health and Pathway through Pain confirmed that their technologies are designed, or will be, to be able to interact with existing NHS systems.

Patient considerations

3.4 Digital technologies can provide quicker access and increase management options for people with non-specific LBP. The patient experts said that quicker access to support can lead to faster improvement in symptoms and can reduce the possibility of acute pain developing to chronic pain. They noted that following a personalised exercise and movement plan could improve mobility, ability to manage pain and mood, and give a sense of control over the condition.

3.5 Patient experts said that reassurance is needed that personal data will be secure. There also need to be appropriate measures in place for reporting adverse events related to using the technologies. They noted that people who are less comfortable or skilled at using digital technology, or unable to read or understand health-related information (including people who cannot read English) need considering. Appropriate alternative support should be provided for them.

3.6 The patient experts advised that patient choice should be a key consideration. They added that people should have the option to remain on a waiting list for a face-to-face appointment if they agree to engage with digital technologies.

3.7 The committee concluded that patient choice and preferences should be taken into consideration when deciding the suitability of digital technologies for managing non-specific LBP. It also noted the importance of codesigning digital technologies with people with LBP. This is to ensure that the content and management options are appropriate and relevant for the users. The companies for ACT for PAIN, getUBetter, Hinge Health and Pathway through Pain said that they have involved people with LBP and healthcare professionals in the development phase of their technologies.

Clinical effectiveness

3.8 The EAG prioritised 12 studies for assessment: 5 randomised controlled trials (RCTs), 1 prospective single-arm trial, 1 prospective cohort study (providing non-comparative data), 2 retrospective cohort studies (providing non-comparative data) and 3 retrospective case series. Only 2 of the studies were done in the UK and 2 other studies included UK participants. The EAG noted that there was considerable uncertainty about the generalisability of the evidence to the UK NHS setting. It stated that there was limited clinical and economic evidence for acceptance and commitment (ACT) therapy in the UK and no studies using ACT for PAIN were identified. The committee noted that there was no evidence of harm or safety concerns. So, it recommended using ACT for PAIN, getUBetter, Hinge Health, Kaia, Pathway through Pain, selfBACK and SupportBack in the NHS while more evidence is being generated. For the other 2 technologies (Ascenti Reach and Phio Engage), there was no evidence or company engagement, so the committee recommended their use only in research.

3.9 The evidence from the prioritised studies reported on 47 different outcomes, including function, pain self-efficacy, intervention adherence and adverse event. The EAG suggested the evidence showed that when compared with standard care alone, digital technologies used with standard care may be effective in terms of improving pain and physical function outcomes. But the range of outcome measures used across the trials made it difficult to compare the digital technologies. Evidence was also limited to short-term effect, with no comparative data for outcomes beyond 3 months. The committee noted that there was no evidence to suggest that technologies were unsafe. It advised that standardised data be collected for future evaluation.

3.10 The committee noted that clinical evidence showed variability in the way adherence was measured and the reported levels of engagement. The clinical experts stated that reported adherence levels were similar to that seen in clinical practice. It was informed that, because of the recurrent nature of LBP, people might stop using a technology when their symptoms improve but use it again if symptoms return. A patient expert said that using digital technologies might be fairly new to people, and that they might experience some challenges. The committee acknowledged that significant effort is needed from people with LBP to complete exercise programmes. It said that the companies should ensure that nudging features are in place to prompt people to engage with the technologies. The committee concluded that more evidence is needed on short-term (30 days) and long-term (6 to 12 months) adherence rates.

Equality considerations

3.11 Digital technologies for managing non-specific LBP may not be suitable for everyone, including people who:

- have limited access to devices or an internet connection
- are less comfortable or skilled at using digital technology

- are unable to read or understand health-related information (including people who cannot read English)
- have a visual impairment
- have problems with manual dexterity.

The committee concluded that face-to-face treatment options should be available when digital technologies are not suitable, and companies should consider providing translations.

Costs and resource use

3.12 Early economic modelling using a simple cost-utility model suggested that digital technologies for managing non-specific LBP may be cost effective when used alongside standard care. Base-case results showed the technologies alongside standard care were cost saving by an estimated £84 per person, with a quality-adjusted life year (QALY) gain of 0.01 compared with standard care alone. This was using a threshold of £20,000 per QALY. The analyses were done using an NHS and personal social services perspective. The base-case results were supported by sensitivity and scenario analyses. The economic model used a 1-year time horizon because of uncertainty in the long-term treatment benefits and the risk of pain relapses, particularly for people with chronic LBP.

3.13 The EAG acknowledged that, because of limited evidence, the model did not have a specific placement in the clinical pathway and that different placement may lead to different reported outcomes. The model included costs of the technologies, healthcare professional time, other health services use and medication. The details of the assumptions used in the model are outlined in table 8.2 of the assessment report on the NICE website. The EAG noted that the main drivers of the model were the cost of the technology, incremental utility, proportion of people engaged with the technology, reduction in physiotherapy referral and number of physiotherapy appointments after referral. The EAG excluded training and

implementation costs from the model because of uncertainty in the level of resource use needed.

3.14 The committee noted that the evidence informing the cost model was limited but that there was plausibility of cost effectiveness. It concluded that it was appropriate to recommend some technologies for conditional use within the NHS while more evidence is being generated.

Evidence gap review

3.15 No evidence was identified for Ascenti Reach, ACT for PAIN or Phio Engage. For the remaining technologies, evidence gaps were identified in population demographics, clinical effectiveness, treatment adherence and healthcare resource use. The committee concluded that there was some evidence of potential benefit to support recommending 7 of the digital technologies for managing non-specific LBP in the NHS with evidence generation, once appropriate regulatory approval is in place. The key evidence gaps were:

- Population: the EAG noted that some clinical studies were excluded because they had an unspecified population. More evidence generation should clearly report population characteristics particularly type of LBP (chronic or acute, specific or non-specific) and pain severity at baseline. This will ensure that data collected captures people with sciatica and back-related leg pain so that this data can be easily extracted and excluded from the analysis.
- Outcomes: comparative evidence identified a wide range of key outcome measures used across the trials, making comparison of the digital technologies difficult. Also, published evidence was not available for most of the outcomes in the scope of this evaluation. Evidence generation should include the use of consistent measures for key outcomes such as pain score and health-related quality of life (Musculoskeletal Health Questionnaire and EQ-5D-5L) to enable comparison of different technologies.

- Adherence: studies that did report adherence varied in the definition of adherence and in the methods used to measure it, making comparisons difficult. More evidence generation should report consistent measures of adherence and reasons for stopping should be recorded.
- Referral: evidence is lacking on the referral setting (referred or self-referred) and the place of the digital technologies in the clinical pathway. It is unclear whether this affects the effectiveness of the digital technologies. There is scarce evidence on the effect of digital technologies on referral rates for other services such as imaging, physiotherapy, surgery or emergency department attendances.
- Resource use: more evidence generation is needed on healthcare resource use, including training and implementation associated with different types of digital technologies, especially those providing psychological treatment.

4 Committee members and NICE project team

Committee members

This topic was considered by NICE's medical technologies 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 the medical technologies advisory committee meetings, which include the names of the members who attended and their declarations of interests, are posted on the NICE website.

Additional specialist committee members took part in the discussions and provided expert advice for this topic:

Specialist committee members

Dr Adrian Chudyk

NIHR Clinical Lecturer in General Practice, Keele University

Mr Ben Wanless

Consultant Physiotherapist, St George's University Hospital NHS Trust

Dr Christopher McCarthy

Associate Professor of Physiotherapy (Reader)/ Clinical Fellow, Manchester Metropolitan University

Ms Doré Young

Advanced MSK Physiotherapy Practitioner, Manchester University NHS Foundation Trust

Prof Jonathan Hill

Professor of Physiotherapy, Keele University

Ms Suzanne McIlroy

Consultant Physiotherapist, King's College Hospital NHS Foundation Trust

Iain Neilson

Lay member

Vivian Brown

Lay member

NICE project team

Each early value assessment topic is assigned to a team consisting of 1 or more health technology assessment analysts (who act as technical leads for the topic), a health technology assessment adviser and a project manager.

Oyewumi Afolabi and Evan Campbell

Health technology assessment analyst

Kimberley Carter

Health technology assessment adviser

Catherine Pank

Project manager

ISBN: