NATIONAL INSTITUTE FOR HEALTH AND CARE EXCELLENCE

Medical Technologies Evaluation Programme

Digital technologies for managing low back pain: early value assessment

Final scope

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1 Introduction

The topic has been identified by NICE for consideration for early value assessment (EVA). The objective of EVA is to identify promising technologies in health and social care where there is greatest need and enable earlier conditional access while informing further evidence generation. The evidence developed will demonstrate if the expected benefits of the technologies are realised and inform a final NICE evaluation and decision on the routine use of the technology in the NHS.

NICE's topic selection oversight panel ratified digital technology for managing low back pain (LBP) as potentially suitable for an EVA by the medical technologies evaluation programme (MTEP).

A list of abbreviations is provided in appendix A.

2 Description of the technologies

This section describes the properties of the digital technologies for managing LBP based on information provided to NICE by manufacturers and experts and information available in the public domain. NICE has not conducted an independent evaluation of this description.

2.1 Purpose of the medical technology

LBP is a common musculoskeletal (MSK) condition which affects a significant proportion of people in the UK. It increases in prevalence with age and has a negative impact on health and national productivity. Versus Arthritis estimates that 11 million people in the UK experience LBP in any given year with approximately 60% experiencing severe cases. LBP can be acute or chronic. Acute LBP is defined as that lasting less than 3 months and chronic LBP as lasting 3 months or more. Non-specific LBP describes pain not attributable to

an underlying cause and is sometimes referred to in literature as ‘mechanical’, ‘musculoskeletal’ or ‘simple’ (NICE clinical knowledge summaries back pain – low [without radiculopathy]).

LBP is a leading and long-standing cause of morbidity and is attributable to 1,434.66 years lived with disability per 100,000 population. Over 30 million working days are lost due to MSK conditions every year in the UK and they account for 30% of GP consultations in England (NHS Long Term Plan). The majority of non-urgent LBP cases are managed in primary or community care, which has limited workforce capacity and resources to meet the needs of patients. Provision of services for MSK-related pain varies across the UK and there is an opportunity to integrate digital technology to increase access and reduce waiting lists by promoting supported self-management.

Digital technologies for managing LBP can provide rapid access to specialist advice and guidance, remote pain management support including physical activity recommendations and psychological therapy via web-based applications and digital platforms. These technologies offer greater flexibility as individuals can work through the recommendations in their own time with varying levels of health practitioner support. The use of these technologies could reduce the number of GP or first contact practitioner (FCP) visits and the need for onward referral to MSK providers, support recovery, improve psychological impact of pain and aid quicker return to full activity.

2.2 Product properties

This scope includes digital technologies for managing LBP. For this EVA, NICE will consider digital technology for LBP that:

- are intended for use by people aged 16 and over
- offers support to help people manage their symptoms, this could include:
    - information and education on LBP
    - advice about being physically active
    - psychological therapies and support
    - exercise recommendations for LBP
    - advice about remaining at or returning to work
    - signposting to other helpful resources for people with LBP
- meet the standards within the digital technology assessment criteria (DTAC), including the criteria to have a CE or UKCA mark where required. Products may also be considered if they are actively working towards required CE or UKCA mark and meet all other standards within the DTAC
- has support from healthcare professionals such as physiotherapists, pain management specialists and clinical psychologists

- will be available for use in the NHS.

In total, 8 digital technologies for managing LBP are included in the scope. The final list of included technologies may be subject to change.

ACTForPAIN (Pain Medicine Specialist Ltd)

ACTForPAIN is a chronic pain psychological self-management program based on acceptance and commitment therapy. It can be accessed via a mobile phone, tablet or computer. ACTForPAIN is supported by pain specialists and psychologists who provide email advice and guidance. The program has a built-in digital pain management assessment questionnaire which can be applied at any time to monitor progress.

Ascenti Reach (Ascenti)

Ascenti Reach is an app-based physiotherapy service that provides users with the tools to manage their own health. It requires users to complete a 10-minute online assessment that covers symptoms, pain history, lifestyle and emotional wellbeing. Based on the responses, a personalised exercise plan is received with set daily reminders, progress tracking and the ability to chat with a physiotherapist.

getUBetter (getUBetter)

getUBetter is a digital therapeutic delivering and enabling patients to self-manage their recovery from all common MSK injuries and conditions by following a recovery and prevention pathway defined by their local healthcare provider alongside evidence based national guidelines. getUBetter helps the NHS at a regional level (Integrated Care Systems/Health Boards) to provide digitally enabled self-management pathways across their whole system for the benefit of their patients. It is intended to help patients during their recovery, effectively self-manage and prevent over treatment. getUBetter is provided as one app that can be delivered via mobile or web application. It can be accessed via self-referral or provided by clinical teams. getUBetter allows self-referral to local third-party MSK tools such as ESCAPE-pain and NHS services. It provides questionnaires, nudges, video content and risk stratification to guide the user. getUBetter is integrated with GP systems and has real-time data analytics dashboard to monitor adoption.

Hinge Health Digital MSK Clinic (Hinge Health)

Hinge Health is a digital therapeutic that aims to reduces MSK pain by pairing advanced wearable sensors and computer vision technology with a clinical care team of physiotherapists, physicians and health coaches. The care team

can monitor a person's engagement and adherence to program activity from a clinical team dashboard. Hinge Health's digital physiotherapy solution includes motion assessments to measure a person's functional ability across flexibility and balance to inform a personalised care plan. It also enables expanded exercise tracking and enhanced clinical care programs that may help improve rehabilitation of difficult-to-treat areas. Hinge Health Digital MSK Clinic provides a range of programs for various stages of the MSK care pathway including programs for acute and chronic pain.

Kaia App (Kaia Health)

Kaia App is a digital therapeutic for people with chronic MSK pain including back, hip, and knee pain. For back pain, Kaia App has three modules: back pain-specific education, physiotherapy and mindfulness techniques. The educational module includes general pain-related and back-specific information. Exercises available within the app are ranked depending on difficulty and adopted to individual's fitness level based on feedback. The mindfulness module is delivered as an audio content. The content for an individual consists of all three modules and is updated daily. The technology aims to support people with chronic pain and those seeking a proactive routine to stay pain free.

Pathway through pain (Wellmind Health)

Pathway through Pain is a digital therapeutic treatment that delivers all elements of an intensive Pain Management Programme (PMP) in a web-based format. It has two main elements: a patient facing tool that offers pain management treatment and a management portal that allows healthcare providers and commissioners access to real-time detailed user progress and outcomes data. Pathway through Pain is delivered by a multidisciplinary team on pre-recorded video that include physiotherapists and clinical psychologists in NHS face-to-face settings. The technology aims to promote behaviour change and reduce the impact of chronic pain on functional ability.

All healthcare professionals involved in a person's care has a unique log-in and can monitor progress, review reported self-assessed disability, health, depression and anxiety outcome scores through a fully integrated, real-time, secure web-based management portal. Users can also request access to their healthcare professional throughout their treatment by contacting the helpline or via an automated notification system through the program interface.

selfBACK (SelfBack Consortium)

selfBACK is a digital therapeutic for self-management of non-specific LBP. The selfBACK app provides participants with weekly tailored self-

management plans that includes recommendation on number of steps per day, educational material, and a program for strength and flexibility exercises. This plan is tailored to each participant based on the baseline questionnaire and a range of patient characteristics, including information from a physical activity-detecting wristband worn by the participant. selfBACK uses data about the current participant case along with knowledge about previous or similar participant cases to tailor the self-management plan to the current individual with LBP. selfBACK is intended for use as a supplement to usual care and not to replace follow-up with a health care professional.

SupportBack (University of Southampton)

SupportBack is an internet-based intervention designed to support patients to self-manage their LBP following consultation in primary care. It is designed to provide advice and encourage physical activity. It can be used by people with both acute and persistent LBP. It is developed to be used in addition to usual care either as a stand-alone internet intervention or in combination with physiotherapist telephone support.

3 Target conditions

The target population for this assessment is people aged 16 years and over with non-specific LBP.

LBP is soreness or stiffness in the back, between the bottom of the rib cage and the top of the legs. It is characterised by pain and discomfort with or without leg pain. Episodes of back pain usually do not last long and rapid improvements in pain and disability can be seen within a few weeks to a few months. Most back pain episodes get better with initial primary or community care management without the need for investigations or referral to specialist services, up to one-third of people have persistent back pain of at least moderate intensity a year after an acute episode needing care, and episodes of back pain often recur (NICE guideline on low back pain and sciatica in over 16s: assessment and management). About 5 out of every 10 people with back pain will get better in less than 6 months. Afterwards, 2 out of every 10 people will have mild back pain sometimes and 3 out of every 10 people will have more severe problems that need more treatments (Versus Arthritis).

The most common LBP is referred to as ‘non-specific’ which means the pain is not attributable to an underlying cause like an infection, a fracture or a disease such as cancer. Risk factors for non-specific LBP include obesity, physical inactivity, occupational factors (such as heavy lifting, bending or twisting) and stressful life events or depression (NICE clinical knowledge summary, 2022). People with physically demanding jobs, physical and mental

comorbidities, smokers and obese individuals are at the greatest risk of reporting LBP (Hartvigsen et al. 2018). The focus of this EVA is on non-specific LBP which can be acute (lasting up to 3 months) or chronic (lasting 3 months or more).

4 Care pathway

NICE's guideline on low back pain and sciatica in over 16s: assessment and management categorises the treatment for LBP into non-invasive and invasive treatments. Non-invasive treatments are either non-pharmacological or pharmacological interventions and invasive treatments are either non-surgical or surgical interventions. The guideline recommends consideration of several non-pharmacological interventions for treating LBP including:

- Self-management – provision of advice and information at all steps of the treatment pathway
- Exercise – group exercise programme for people with specific episodes of flare-up of LBP
- Manual therapies – spinal manipulation, mobilisation or soft tissue technique such as massage offered only as part of a treatment package including exercise with or without psychological therapy
- Psychological therapy – psychological therapies using cognitive behavioural approach only as part of a treatment package including exercise with or without manual therapy
- Combined physical and psychological programmes – for people with persistent LBP when they have significant psychosocial obstacles to recovery or when previous treatments have not been effective
- Return to work programmes – provision of advice about remaining in or returning to work.

It is recommended that these interventions are tailored to individual's specific needs, preferences and capabilities. For chronic primary pain, acceptance and commitment therapy (ACT) or cognitive behavioural therapy (CBT) delivered by healthcare professionals with appropriate training is also recommended (NICE's chronic pain (primary and secondary) in over 16s: assessment of all chronic pain and management of chronic primary pain).

Pharmacological management of LBP includes prescribing oral non-steroidal anti-inflammatory drugs (NSAIDs) or weak opioids (with or without

paracetamol) for managing acute LBP only if an NSAIDs is contraindicated, not tolerated or has been ineffective.

NHS musculoskeletal digital playbook describes different steps along the MSK pathway in which digital technology can be used. These includes self-management, referral management, primary care, diagnostics, outpatients, surgery/inpatient, community service and rehabilitation, discharge and patient-initiated follow-up (PIFU) after discharge. The self-management step includes the provision of digital support for people seeking self-help resources when they need it the most. The referral management step involves the provision of advice, guidance and self-referral for people to receive virtual advice easily.

Potential place of digital technologies for managing LBP in the care pathway

Digital technologies for managing LBP would be offered via self-referral or after clinical assessment and diagnosis. It would be an alternative or addition to standard care. The place in the care pathway depends on the type of LBP, healthcare professional assessment, the content of the intervention, individual's specific needs and preferences. Digital technologies that are eligible for self-referral will be those with integrated assessment and risk stratification to ensure red flags are picked up and the right self-management advice is given to the right people. Red flags are symptoms that may indicate a serious underlying cause such as cauda equina syndrome, spinal malignancy, vertebral fracture or spinal infection.

Technologies that provide psychological support may not be suitable for people with acute LBP. Digital technologies for managing LBP for this EVA would also be an integral part of all steps of the MSK pathway where emphasis is on management and support.

5 Patient issues and preferences

Digital technologies for LBP are delivered via mobile phones, tablets or computers and can therefore be accessed remotely. It could be used to manage waiting lists by providing practical and emotional support for people with LBP and facilitate quicker access to healthcare professional where necessary. It can reduce face-to-face appointments and appeal to people if they have sufficient digital skills and prefer to access healthcare remotely. Digital technologies for LBP may also provide people with options to better self-manage and be more involved in their recovery and treatment decisions.

Some people may prefer face-to-face treatment and follow-up and choose not to use digital technologies. There may be some concerns about the level of support provided by digital technologies for LBP as well as concerns about

data security and quality control. People have the right to make informed decisions about their care, including the use of digital technologies.

6 Comparator

Digital technologies for LBP would be offered as an alternative or addition to non-pharmacological interventions and additional to pharmacological interventions. The comparator is standard care which varies significantly across primary and community care.

7 Scope of the assessment

Table 1 Scope of the assessment

Population	People aged 16 years and over with non-specific LBP* that are eligible for digital technology management
Subgroups	If the evidence allows, the following subgroups will be considered: • people with acute LBP • people with chronic LBP
Interventions (proposed technologies)	Digital technology for LBP that provide self-management and/or phycological support. This includes: • ACTForPain • Ascenti • getUBetter • Hinge Health Digital MSK Clinic • Kaia • Pathway through Pain • selfBACK • SupportBack
Comparator	Standard care for managing LBP
Healthcare setting	Outpatient clinics, primary care, community care or home-based care
Outcomes	Intermediate measures for consideration may include: • Improvements in functional outcomes • Treatment satisfaction and engagement • Pain self-efficacy • Change in number appointments • Time to recovery (for acute LBP) • Patient choice and preference • Work productivity/Return to full activity

	• Intervention adherence and completion (number of exercise/therapy sessions completed, interaction with health professionals, education contents reviewed) • Activation measures • Intervention-related adverse effect • Clinician satisfaction
	Clinical outcomes for consideration may include: • Reduction in pain level/ pain improvement • Reduced physiotherapy referrals • Reduced treatment waiting list • Self-removal from waiting list • Reduced pharmacological management • Reoccurrence of LBP • Reduced imaging referrals • Quicker discharge • Reduced surgical referrals • Reduced emergency department attendances
	Patient-reported outcomes for consideration may include: • Health-related quality of life • Pain scales (Numerical Pain Rating Scale / Visual Analogue Scale) • MSK health questionnaire • Back specific disability score (Oswestry Disability Index for LBP) • Patient experience

	Costs will be considered from an NHS and Personal Social Services perspective. Costs for consideration should include:
	• Costs of the technologies including licence fees
	• Costs of the required kit (such as mobile phones) including internet access
	• Cost of other resource use
	  ○ GP or secondary care appointments
	  ○ Medication use
	  ○ Cost of physiotherapy/MSK provider
	  ○ Cost of psychological therapy (i.e., CBT or ACT)
	  ○ Healthcare professional grade and time

Time horizon	The time horizon for estimating the clinical and economic value should be sufficiently long to reflect any differences in costs or outcomes between the technologies being compared.

*The following are beyond the scope of this assessment, population with:

- specific causes of LBP for example cancer, infection, trauma, or inflammatory disease such as spondylarthritis
- sciatica
- pain associated with nerve root entrapment

This EVA will evaluate the proposed technologies as similar in terms of providing management and support options for LBP whilst considering but not evaluating the different features of each technology.

Intermediate and clinical outcomes have been ranked and listed in order of prioritisation by clinical experts. This may be taken into consideration when developing a conceptual health economic model for this assessment and some outcomes may be excluded if there are no available evidence.

8 Other issues for consideration

Characteristics of digital technologies

- The digital technologies for LBP included in the scope may differ in terms of mode of delivery (mobile applications, computer), type of intervention (exercise or psychological therapy), and the frequency and level of support from healthcare professionals.

Evidence

- This assessment will look across a range of evidence types including RCTs and real-world evidence. Evidence considered will include evidence of clinical effectiveness, comparative outcomes to current standard care. The amount and level of evidence for each of the technologies may vary and it is likely that the different technologies will require various levels of additional evidence.
- Some of the technologies assess a range of MSK conditions and additional evidence and subgroup analysis may be required for population with LBP.
- This assessment will evaluate the clinical and potential cost effectiveness of digital technologies as an alternative or addition to standard care in the NHS. This will include evaluating whether technologies have equal or superior outcomes to alternative treatments offered in NHS services for managing LBP.

Care pathway

- Digital technologies for managing LBP can be used at different points in the care pathway depending on the management and support content of the intervention. This should align with NICE guidelines and be appropriate for the type of LBP and the step in the care pathway for which it is intended to be used.

9 Potential 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.

LBP increases in prevalence with age and adults aged 45 years and over have an increased risk of having chronic low back pain. MSK pain disproportionately affects people from some ethnic minority backgrounds.

Digital technologies are delivered through a mobile phone, tablet, or computer. People will need regular access to a device with internet access to use the technologies. Additional support and resources may therefore be needed for people who are unfamiliar with digital technologies or do not have access to smart devices or the internet. People with visual or cognitive impairment, problems with manual dexterity, a learning disability or who are unable to read or understand health-related information (including people who cannot read English) may need additional support to use the technologies.

People's ethnic, religious and cultural background may affect their views of digital technologies for managing LBP. People have the right to make informed decisions about their care, including the use of digital technologies. Healthcare professionals should discuss the language and cultural content of the technologies with patients.

Age, disability, race and religion or belief are protected characteristics under the Equality Act (2010).

10 Potential implementation issues

Risk of harm

Digital technologies must be able to identify red flags and potential risks for people with LBP. Initial assessment and risk stratification is important to ensure the right advice and support is given to the right people. Some digital technologies have inbuilt processes to flag the need for more intervention.

This is important to consider when choosing digital technology for managing LBP and the step in the pathway for which it is most appropriate.

11 Authors

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Appendix A Abbreviations

ACT	Acceptance and commitment therapy
AI	Artificial intelligence
CBT	Cognitive behavioural therapy
DTAC	Digital technology assessment criteria
EVA	Early value assessment
GP	General practice
LBP	Low back pain
MSK	Musculoskeletal
MTEP	Medical technologies evaluation Programme
NSAIDs	Non-steroidal anti-inflammatory drugs
PIFU	Patient-initiated follow-up
PMP	Pain management programme