NICE National Institute for Health and Care Excellence

NICE guidance

AposHealth for knee osteoarthritis

Medical technologies guidance
Published: 11 April 2023

www.nice.org.uk/guidance/mtg76

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.

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This guidance replaces MIB284.

1 Recommendations

1.1 AposHealth is recommended as a cost-saving option to manage knee osteoarthritis in adults only if:

- non-surgical standard care has not worked well enough and
- their condition meets the referral criteria for total knee replacement surgery but they do not want surgery and
- data is collected on the person's quality of life, health resource use and if they have knee replacement surgery in the long term.

1.2 Further research is recommended on AposHealth for:

- people with knee osteoarthritis that meets the referral criteria for total knee replacement surgery but who cannot have surgery because it would be unsafe
- people whose condition does not meet the referral criteria for total knee replacement surgery.

Find out more in the further research section in this guidance.

Why the committee made these recommendations

Clinical evidence from a high-quality trial shows that AposHealth improves scores for measuring pain, stiffness and function when compared with a sham device in people with symptomatic knee osteoarthritis. But it is uncertain whether the improvements are clinically meaningful in terms of reducing symptoms. Two studies compared AposHealth with a sham device. There is a lack of evidence directly comparing AposHealth with standard care, but this comparison is difficult because standard care is hard to define for this condition. There is limited clinical evidence for people who cannot have surgery because it would be unsafe, such as people who are frail and at a high risk of falls.

The evidence from studies that did not compare AposHealth with another treatment or

sham device suggests that it improves pain, stiffness and function compared with before using AposHealth. Clinical and patient experience of using AposHealth agreed with this.

There is a lack of comparative evidence looking at knee surgery delay. Non-comparative clinical evidence also suggests that AposHealth may delay the need for knee surgery, but the length of this delay is uncertain. The delay seen in the evidence reflects the real-world experience of clinicians and patients who are using the technology in the NHS.

Cost-comparison analyses show that the potential cost savings from AposHealth mainly come from reduced standard care costs and reduced knee replacement surgeries. The analyses also suggest that AposHealth is cost saving by £1,958 per person when compared with standard care if knee surgery is delayed for 5 years. Because the evidence for the potential cost savings is limited, further data collection is recommended to understand if cost savings are made once AposHealth is used in the NHS.

There are no knee replacement costs for people who cannot have surgery because it would be unsafe, so both the potential cost saving and clinical benefit are uncertain. Therefore, AposHealth is not recommended for people who cannot have surgery, and more research is recommended.

2 The technology

Technology

2.1 AposHealth (AposHealth, previously AposTherapy) is a non-invasive device worn on the feet. The device consists of a pair of AposHealth shoes with 2 curved pods (pertupods) on the heel and forefoot of each shoe. The pertupods are securely attached to tracks on the bottom of the shoe with screws. Positioning of the pertupods is done by trained healthcare professionals and can be aided by gait analysis software or hardware.

2.2 The AposHealth 4-step treatment plan lasts 1 year and consists of an initial patient assessment, personalisation of the device, at-home treatment and ongoing monitoring. The at-home treatment step involves the person wearing the device for short periods of time during daily activities, for a total of up to 60 minutes per day. People should be offered 1 to 2 follow ups per year after the treatment plan as part of ongoing monitoring if continuing to use AposHealth.

Care pathway

2.3 Treatment of knee osteoarthritis depends on the severity of symptoms. Current treatment options include pharmacological and non-pharmacological treatments.

2.4 Non-pharmacological core treatments for osteoarthritis are therapeutic exercise and weight loss (if appropriate), along with information and support. NICE's guideline on the diagnosis and management of osteoarthritis recommends tailoring information to the individual needs of people with osteoarthritis, their families and carers, ensuring it is in an accessible format. Other non-pharmacological treatment options include manual therapy (such as manipulation, mobilisation or soft tissue techniques) and devices (such as walking aids).

2.5 Pharmacological treatment options include topical and oral non-steroidal anti-inflammatories to relieve pain and inflammation. Intra-articular corticosteroid

injections should be considered when other pharmacological treatments are ineffective or unsuitable, or to support therapeutic exercise. However, these treatments only provide short-term relief and may become less effective as the severity of knee osteoarthritis increases. NICE's interventional procedures guidance on platelet-rich plasma injections for knee osteoarthritis says that this procedure should only be used with special arrangements for clinical governance, consent, and audit or research.

2.6 Referral for knee surgery should be considered for people who experience joint symptoms (such as pain, stiffness, reduced function or progressive joint deformity) that have a substantial impact on their quality of life, and if non-surgical management is ineffective or unsuitable. Clinical assessment should be used when deciding to refer someone for joint replacement, instead of systems that numerically score severity of disease.

Innovative aspects

2.7 AposHealth is intended to improve biomechanics by redistributing pressure away from affected areas and reducing knee pain. On a neuromuscular level, it is designed to re-educate muscles and correct abnormal gait patterns, which can extend to when the person is not actively wearing the device.

Intended use

2.8 AposHealth is intended for use by adults with knee osteoarthritis who have had non-surgical standard care that has not worked well enough.

Costs

2.9 AposHealth costs £875 (excluding VAT) per treatment programme for both knees. The treatment programme includes:

- AposHealth shoes and unlimited parts

- access for healthcare professionals to standardised outcome measures on the AposHealth clinical tracking system
- training for healthcare professionals (typically consisting of 6 hours of theory training, and 5 to 10 observed calibrations delivered as part of routine service provision).

  For more details, see the AposHealth website.

3 Evidence

NICE commissioned an external assessment group (EAG) to review the evidence submitted by the company. This section summarises that review. Full details of all the evidence are in the project documents on the NICE website.

Clinical evidence

The main clinical evidence comprises 29 publications, including 1 randomised controlled trial (RCT)

3.1 The main clinical evidence includes 29 publications (15 full-text papers, 9 abstracts associated with the included full texts, and 5 additional abstracts), covering a total of 19 unique studies. The full-text papers comprise 1 RCT, 1 prospective comparative study with a 2-year follow-up study and 12 non-comparative studies. Drew et al. (2022) reported clinical information from a comparative group at baseline only, so the study was treated as a single-arm observational study and the results were extracted from the AposHealth arm only. The full-text publications include a total of 3,767 people. For full details of the clinical evidence, see the clinical evidence section of the assessment report in the supporting documentation.

Comparative evidence is lacking

3.2 There is a lack of evidence comparing AposHealth with non-surgical standard care treatments. The EAG acknowledged that this may be driven by uncertainties in the care pathway, making it difficult to design and do comparative studies. Both the RCT and prospective comparative study, with a 2-year follow-up study, compared AposHealth with a sham device. The EAG considered the RCT to be of high quality with a low risk of bias. The prospective comparative study allowed people to cross over between the groups after 8 weeks. The EAG stated that the unclear description of this crossover undermined the robustness of the results.

3.3 The other 12 studies are observational and have a high risk of bias. The Western Ontario and McMaster Universities Osteoarthritis Index (WOMAC) scores, 36-item short form (SF-36) questionnaire results and gait outcomes were frequently reported, and the EAG acknowledged that the outcomes reported across the studies were consistent.

Improved pain, function and stiffness

3.4 When AposHealth is compared with a control group, the differences in pain, function and stiffness measured by the WOMAC score are statistically significant and show better outcomes for the AposHealth group. But the EAG noted that it is uncertain whether the improvement shown in the RCT is clinically meaningful. The EAG also noted that the WOMAC scores reported in the studies were not all on the same scale and advised caution when comparing WOMAC scores between studies and interpreting the evidence. Clinical evidence from non-comparative studies shows a consistent improvement in pain, function and stiffness after using AposHealth when compared with baseline and measured by the WOMAC score.

Knee replacement surgery might be delayed or avoided, but the evidence is limited

3.5 Two non-comparative studies included by the EAG had knee replacement surgery as a primary outcome, and only 1 of the studies was based in the UK. The UK-based study reported that 84% of people (305 of 365) using AposHealth whose condition met the criteria for total knee replacement surgery referral did not progress to total knee replacement surgery at 2 years. The other (US-based) study reported that 86% of people (204 of 237) using AposHealth did not progress to total knee replacement surgery at 2 years.

Quality of life, in particular the physical aspects, may be improved

3.6 There is some evidence that AposHealth may improve quality of life, with stronger evidence for improvement to physical aspects. The RCT found no difference between the active and control groups in SF-36 scores. The prospective comparative study reported a significant difference in the physical component summary and total score of the SF-36 questionnaire but reported no difference in the mental component summary. In non-comparative studies, SF-36 scores from baseline to post-treatment follow up for AposHealth showed significant improvements in some sub-scores, but improvements varied between studies.

Standard care resource use might be reduced, but the evidence is limited

3.7 There is limited, low-quality evidence that AposHealth results in reduced standard care resource use. The RCT reported no difference in rates of analgesic use between the active and control groups, and the prospective comparative study reported that the control group used more rescue medication (647 tablets) than the active group (273 tablets). The company submission also included unpublished survey and audit data that suggested AposHealth resulted in a reduction in health resource use.

Cost evidence

AposHealth is cost saving compared with non-surgical standard care at 5 and 10 years according to the company's model

3.8 The company submitted a Markov decision model comparing standard care with and without AposHealth. The model is based on movement of people from standard care (with or without AposHealth) to total knee replacement surgery, and then to total knee replacement surgery of the other knee. The model results were originally reported at a 2-year and 5-year time horizon. However, after

queries from the EAG, the company submitted an additional model with an extended 10-year time horizon. The company model assumes that all people will have 2 follow ups per year in years 2 to 5, and 1 follow up in years 5 to 10. The company's base case showed a cost saving of £1,886 at 5 years and £247 at 10 years. For full details of the cost evidence, see the economic evidence section of the assessment report in the supporting documentation.

The company's model structure is appropriate, with changes to certain parameters

3.9 Key clinical parameters in the company model are the rate of total knee replacement, subsequent total knee replacement on the other knee, postoperative complications and mortality. The EAG added a starting age of 68 years to the model, based on data from the National Joint Registry annual report (2021). The company model assumes the rate of subsequent total knee replacement on the other knee as 0.5% per month, and the rate of total knee replacement revisions as 0.34% per month. The EAG's model includes a slightly lower rate of 0.395% for total knee replacement on the other knee, using the value from Sanders (2017). It also included a lower rate of 0.32% per month for total knee replacement revisions from an alternate data source and added a variable mortality rate as the cohort passes through the model. Total knee replacement costs in the company model are taken from NHS best practice tariffs. But the EAG used alternative NHS reference cost data from 2019 to 2020 (to avoid the impact of COVID-19) and inflated to 2022 to 2023.

AposHealth is cost saving at 5 years, but the model results should be treated with caution

3.10 The EAG base case is that AposHealth is cost saving compared with standard care by £1,958 per person at 5 years, and cost incurring by £46 per person at 10 years. The EAG extended the model further and reported that AposHealth is also cost incurring by £2,032 at 20 years. The EAG noted that cost savings primarily come from a reduction in total knee replacement and reduced subsequent complications and follow up. So, the EAG felt that the model results should be treated with caution because existing evidence for delay to surgery is

limited, as described in the clinical evidence (see the section on knee replacement surgery delay).

Key cost drivers in the model are standard care costs and reduction in standard care because of AposHealth

3.11 The company did a deterministic sensitivity analysis with one-way and two-way tables for key parameters, which were varied by 20%. The EAG repeated this with the amended model and extended it to 20 years. The cost of standard care uses parameter variations based on lower costs from Cole (2022) and a 20% increase from the base-case input. Lower standard care costs before knee surgery are likely to lead to cost savings because fewer costs are accumulated by people who are delaying having surgery. The cost of standard care before total knee replacement is the only parameter that makes the one-way sensitivity analysis cost saving at 20 years. The EAG also emphasised the importance of the reduction to standard care costs because of AposHealth. The EAG reiterated the uncertainty about this evidence, as described in the section on standard care resource use.

AposHealth may be cost saving for people who cannot have knee surgery if standard care costs are reduced by 20%

3.12 The EAG considered an exploratory scenario for people who are unable to have total knee replacement by setting movement of people having surgery in the model to 0%. With the assumption of a 15% reduction in standard care costs, AposHealth is cost incurring by £538 at 5 years and £40 at 20 years. But, if there is a 20% reduction in standard care costs, AposHealth becomes cost saving by £259 at 5 years and £701 at 20 years.

4 Committee discussion

Clinical effectiveness overview

Pain, function and stiffness are improved, but there are uncertainties

4.1 The committee noted that the authors of the randomised controlled trial (RCT) publication said that there was uncertainty in whether the improvements were clinically important. But the committee was reassured by the clinical and patient expert advisers reporting very positive outcomes. A patient expert adviser said that they continue to use the technology effectively as pain relief. The committee acknowledged that the rest of the evidence base is limited in methodological quality, but the outcomes reported across the evidence base are consistent. The committee concluded that AposHealth may lead to improvements in pain, function and stiffness for people with knee osteoarthritis.

Total knee replacement surgery may be delayed, but it is uncertain for how long

4.2 The EAG reported that 2 non-comparative studies based in the US and UK included the rate of total knee replacement as a primary outcome. Drew (2022) and Greene (2022) reported an 86% and 84% rate, respectively, of total knee replacement avoidance for people using AposHealth at 2 years. The clinical and patient expert advisers agreed that these rates reflected their experience of using the technology in the NHS for up to 7 years. The committee noted that the rate of surgery avoidance reported in Greene (2022) may be an overestimation. This is because the study follow up overlapped with the COVID-19 pandemic, when elective surgeries were often put on hold. The committee acknowledged that the clinical evidence was non-comparative and uncertain but accepted the support from clinical and patient expert advisers.

NHS considerations

People referred for AposHealth should meet the referral criteria for total knee replacement surgery

4.3 The committee discussed patient selection and the position of AposHealth in the care pathway. It noted that the clinical evidence does not specify a clear place or patient population for AposHealth in the care pathway. Clinical expert advisers using the technology stated that AposHealth is usually delivered as part of the musculoskeletal secondary care service. They also explained that people must have tried other non-surgical standard care and have met the referral criteria for a total knee replacement. The committee concluded that the appropriate population and place in the care pathway should be if non-surgical standard care has not worked well enough and the person's condition meets the referral criteria for total knee replacement surgery.

AposHealth is an option if a person does not want surgery

4.4 The decision to undergo knee surgery is a shared decision and there are multiple factors involved (see NICE's guidance on shared decision making). A patient expert adviser felt that surgery was not their preferred treatment option because of their young age and negative past experiences in their family. Clinical expert advisers agreed that a person's age, social and economic factors, comorbidities and understanding of the procedure may all influence their decision to have surgery. The committee acknowledged that there are many reasons people may not want surgery, and more strategies to manage symptoms for this group, such as AposHealth, are necessary.

AposHealth may not be suitable for some people, but this is assessed on an individual basis

4.5 The committee discussed patient eligibility and monitoring for AposHealth. It noted that AposHealth may be contraindicated for people with balance issues or especially severe osteoporosis. Clinical expert advisers explained that eligibility

for AposHealth is reviewed on an individual basis. This is to ensure people are not put at risk of falls and can control the instability of the shoes. They also noted that healthcare professionals trained in using AposHealth, such as physiotherapists or podiatrists, continue to assess people's eligibility during follow-up visits through clinical assessment and observational gait analysis. The committee acknowledged that the technology may not be suitable for some people but accepted that healthcare professionals will use clinical judgement when referring and assessing people for AposHealth.

Adherence

Adherence could be improved with AposHealth because of immediate symptom relief

4.6 Clinical expert advisers said they rarely find that people do not use AposHealth as recommended. People are advised to wear the technology at home or at work for short periods of time. A patient expert adviser said that wearing the technology at home was convenient, and that they are eager to wear the device because of an immediate relief of symptoms. Clinical expert advisers noted that the instant symptom relief experienced by people can lead to overuse, which may result in muscle stiffness or soreness if not monitored appropriately. The committee noted that current users are selectively sampled and there is no data on adherence in a wider NHS setting. But it accepted that it is unlikely that people may not use AposHealth as recommended.

AposHealth needs continued use for ongoing benefits

4.7 Clinical experts stated that using the technology daily improves muscle activity around the joint, which can lead to benefits when not actively wearing the technology. After the initial programme, people are advised to use the technology 2 to 4 times a week to remain stable. A patient expert adviser confirmed that wearing the technology as instructed has enabled them to do more exercise outside of the treatment programme. Now they only use the technology in response to acute joint pain or stiffness. The committee acknowledged that

AposHealth may become less effective over time if use is stopped.

Other patient benefits or issues

Other lower limb joints may benefit from AposHealth

4.8 Clinical expert advisers noted that people with knee osteoarthritis often have comorbidities, such as back pain. Clinical expert advisers confirmed that they assess the impact of AposHealth on other lower limb joints during the initial AposHealth assessment to ensure the calibration of the technology is beneficial to all joints. The company noted that there is clinical evidence available for people with lower back and hip pain. This evidence was not presented to the committee or reviewed by the EAG, but the committee was reassured that AposHealth was unlikely to have adverse effects on other joints.

Decision modelling overview

Limited data makes the economic modelling uncertain

4.9 The EAG reported that AposHealth was cost saving at 5 years but became cost incurring at 10 years. The committee accepted that the main cost savings come from reduced total knee replacement surgery. The committee noted that there is limited evidence for reduced total knee replacement beyond 2 years. But it acknowledged that clinical expert advisers who have up to 7 years of experience using the technology also support the plausibility of reduced knee replacement surgery sustained over time. Clinical expert advisers also noted that AposHealth continues to be funded in their local area. The committee concluded that there are still uncertainties about the evidence for delaying total knee replacement surgery, but accepted the potential cost savings for the technology up to 5 years.

Reduced standard care costs is a key driver in the economic model

4.10 The EAG's sensitivity analysis showed that the reduced standard care costs when using AposHealth is one of the main drivers for increasing cost savings in the model. The EAG explained that the assumption of a 15% reduction in standard care costs comes from published clinical evidence showing reduced pain and increased function, and unpublished audit data from the US and UK suggesting a decrease in resource use. A patient expert adviser noted that they have not needed further help from their local service and have used less medication since using the technology. The committee acknowledged that the experience of clinical and patient experts also suggests AposHealth may reduce use of healthcare resources.

Further research

Long-term real-world data is needed on AposHealth's clinical effectiveness and cost benefit

4.11 The committee suggested that real-world data could be collected to determine the clinical effectiveness and cost benefit of AposHealth for people whose condition meets the criteria for surgery but who do not want it over a longer time horizon. The committee noted that there is already a high-quality RCT comparing AposHealth with a sham device and acknowledged that there are difficulties in designing comparative studies because of the uncertainties in the standard care pathway. The committee supported the use of the technology in the NHS alongside the collection of high-quality real-world data, with outcomes including standard care resource use, health-related quality of life, and long-term outcomes such as rates of total knee replacement. The committee suggested that this data could be collected through a high-quality national registry (such as the National Joint Registry). The committee agreed that long-term data collection over 5 to 10 years will help establish the cost benefits of AposHealth.

4.12 The committee recommended that further research is needed for people whose condition meets the referral criteria for knee replacement surgery, but who

cannot have surgery because it would be unsafe, and for the wider population of people with knee osteoarthritis because of the uncertainty around the clinical and cost evidence. The committee agreed that research with outcomes including standard care resource use, health-related quality of life, and long-term outcomes such as rates of total knee replacement should be collected. It noted that health-related quality of life data may be collected using standardised patient-reported outcome measures, such as the EQ-5D.

5 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 appraised. 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, which include the names of the members who attended and their declarations of interests, are posted on the NICE website.

NICE project team

Each medical technologies guidance 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.

Amy Barr and Dionne Bowie
Health technology assessment analysts

Kimberley Carter
Health technology assessment adviser

Victoria Fitton and Catherine Pank
Project managers

ISBN: 978-1-4731-5115-4

Accreditation