NATIONAL INSTITUTE FOR HEALTH AND CARE EXCELLENCE

Draft guidance

AposHealth for knee osteoarthritis

How we develop NICE medical technologies guidance

If a technology is recommended for use, the specific recommendations are not intended to limit use of other relevant technologies that may offer similar advantages. If the technology is recommended for use in research, the recommendations are not intended to preclude the use of the technology but to identify further evidence which, after evaluation, could support a recommendation for wider adoption.

1 Recommendations

1.1 AposHealth is recommended as a cost saving option to manage knee osteoarthritis in people 16 years and over 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 cannot have or do not want surgery.

1.2 Further data collection is recommended on quality of life, health resource use and long-term rates of knee replacement for people with knee osteoarthritis that meets the criteria for total knee replacement surgery, but who cannot have or do not want surgery and are using AposHealth in the NHS.

1.3 Further research or data collection is recommended on AposHealth for people with knee osteoarthritis that 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 randomised controlled 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 comparative studies compared AposHealth with a sham device. There is a lack of evidence directly comparing AposHealth with standard care. However, this comparison is difficult because standard care is difficult to define for this condition. 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 expert adviser experience of using AposHealth agreed with this.

The 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 clinical and patient experts who are using the technology in the NHS.

The potential cost savings from AposHealth mainly come from reduced standard care costs and a reduction in knee replacement surgery. Cost analyses suggest AposHealth is cost saving by £1,958 per person when compared with standard care over 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.

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.

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, and 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 (NSAIDs) 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

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 reduce 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 people 16 years and over 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 consists of 6 hours theory training, and 5 to 10 observed calibrations that are delivered as part of routine service provision).

For more details, see the website for AposHealth for osteoarthritis of the knee.

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

Summary of the evidence

3.1 The main clinical evidence comprises 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 randomised controlled trial (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 section 4 of the assessment report in the supporting documentation.

Comparative evidence

3.2 There is a lack of evidence comparing AposHealth to 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 conduct 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 cross over undermined the robustness of the results.

Observational evidence

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

Outcomes

Pain, function and stiffness

3.4 AposHealth improves pain, function and stiffness. 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 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. The EAG also noted that it is uncertain whether the improvement shown in the RCT is clinically meaningful. 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

3.5 There is limited evidence suggesting that AposHealth can delay or avoid knee replacement surgery. 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) whose condition met the criteria for total knee replacement surgery referral, and used AposHealth did not progress to total knee replacement surgery at 2 years. The other (US based) study reported that 86% (204 of 237) of people using AposHealth did not progress to total knee replacement surgery at 2 years.

Quality of life

3.6 There is some evidence that AposHealth may improve quality of life, with stronger evidence for improvements to physical aspects. The RCT found no difference between the active and control groups in SF-36 questionnaire 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 questionnaire

scores from baseline to post-treatment follow up for AposHealth showed significant improvements in some sub-scores but improvements varied between studies.

Resource use

3.7 There is limited, low quality evidence that AposHealth results in a reduction in 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

Company base case

3.8 The company's model finds AposHealth cost saving compared with non-surgical standard care at 5 and 10 years. The company submitted a Markov decision model comparing standard care with standard care with 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 receive 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 section 9 of the assessment report in the supporting documentation.

Clinical and cost parameters

3.9 The company's model structure is considered appropriate, but the EAG made changes to certain parameters in the model. Key clinical

parameters in the company model are the rate of total knee replacement, subsequent total knee replacement on the other knee, post-operative complications and mortality. The EAG added a starting age of 68 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.

EAG base case

3.10 The EAG and company models have some differences but have similar findings at 5 and 10 years. The EAG base case is cost saving for AposHealth 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 section 3.5.

Sensitivity analysis and additional scenarios

3.11 The cost of standard care, and reduction in standard care because of AposHealth are key cost drivers in the model. The company carried out 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. This results in the cost of standard care before total knee replacement being the only parameter that makes the sensitivity analysis cost saving at 20 years. The EAG emphasised the importance of standard care costs, and the reduction to these costs because of AposHealth. The EAG reiterated the uncertainty around this evidence as described in section 3.7.

3.12 AposHealth may be cost saving for people who do not want or cannot have knee surgery if standard care costs are reduced by 20%. The EAG considered a scenario for people who do not want or 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

4.1 The clinical evidence shows that AposHealth improves pain, function and stiffness, but there are some uncertainties. The committee noted that the authors of the randomised controlled trial (RCT) publication said 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.

Knee replacement surgery

4.2 AposHealth may delay total knee replacement surgery, but it is uncertain for how long. 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 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 clinical evidence was non-comparative but acknowledged the support from clinical and patient expert advisers.

NHS considerations

Patient selection

4.3 People referred for AposHealth should meet the referral criteria for total knee replacement surgery. The committee discussed patient selection and the position of AposHealth in the care pathway. The committee noted that the clinical evidence doesn't 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. People must have tried other non-surgical standard care and have met the referral criteria for a total knee replacement consultation. Clinical expert advisers also explained that AposHealth may be contraindicated for people with balance issues and people with especially severe osteoporosis but noted that eligibility is reviewed on an individual basis. The committee acknowledged that the technology may not be suitable for certain people but accepted that healthcare professionals will use clinical judgement when referring people for AposHealth.

4.4 The decision to undergo knee surgery is a shared decision making process and there are multiple factors involved (see NICE's guidance on shared decision making). A patient expert adviser felt that surgery wasn't 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 or cannot have surgery, and more strategies to manage symptoms for this group, such as AposHealth, are necessary.

Adherence

4.5 AposHealth can provide immediate symptom relief, which may encourage adherence for people using it. Clinical expert advisers said that they rarely find 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 in symptoms. Clinical expert advisers noted that the instant symptom relief experienced by people can lead to over-use 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 accepted that it is unlikely that people may not use AposHealth as recommended.

4.6 AposHealth needs continued use for ongoing benefits. 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, and now only uses the technology in response to acute joint pain or stiffness. The committee

acknowledged that the treatment may become less effective over time if use is stopped.

Other patient benefits or issues

4.7 AposHealth may benefit other lower limb joints. 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 use of AposHealth was unlikely to have adverse effects on other joints.

Decision modelling overview

4.8 There are uncertainties in the economic modelling because of limited data. 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 a reduction in total knee replacement surgery. The committee noted that there is limited evidence for a reduction in total knee replacement beyond 2 years. But it acknowledged that clinical expert advisers who have up to 7 years of experience delivering the technology also support the plausibility of reductions in 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 around the evidence for delaying total knee replacement surgery but accepted the potential cost savings for the technology up to 5 years.

4.9 The EAG's sensitivity analysis showed that the reduction in standard care costs when using AposHealth is one of the main drivers in the cost 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 haven't needed further help from their local service and have used less medication since using the technology. The committee acknowledged that the clinical and patient expert adviser user experience is positive for reducing use of healthcare services

Further research

4.10 The committee suggested that real-world data could be collected to determine the clinical effectiveness and cost benefit of AposHealth over a longer time horizon. The committee noted that there is 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 agreed that 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 may be appropriate. The committee recommended that data should continue to be collected for the wider population of people with knee osteoarthritis, as well as people who have met the referral criteria for a total knee replacement. It noted that health-related quality of life data may be collected using standardised patient reported outcome measures, such as the EQ-5D. The committee agreed that long-term data collection over 5 to 10 years will help to establish the cost benefits of AposHealth over a longer time horizon. The committee suggested that this data could be collected through a high-quality national registry (such as the National Joint Registry).

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

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