NATIONAL INSTITUTE FOR HEALTH AND CARE EXCELLENCE

Medical technology guidance scope

AposHealth for knee osteoarthritis

1 Technology

1.1 Description of the technology

AposHealth device

AposHealth (AposHealth, previously AposTherapy) is a non-invasive foot-worn device which aims to improve the pathological walking patterns of people with knee osteoarthritis, a condition that causes the joint to become painful and stiff.

The device consists of a pair of AposHealth shoes with two curved pods (pertupods) on the heal and forefoot of each shoe. The pertupods are positioned and securely attached to tracks on the bottom of the shoe with screws. Pertupods are available in different sizes and levels of hardness. The height can be changed by adding spacers and weight can be increased by adding weighted discs. Gait analysis software is used by trained healthcare professionals to position the pertupods on the device.

The AposHealth shoes are available with a Velcro fastening, or with a lace fastening depending on the person's hip flexibility, finger dexterity, foot width and preference.

AposHealth treatment plan

The AposHealth treatment plan consists of 4 steps over a 1-year treatment period:

- Step 1: initial assessment. An AposHealth trained healthcare professional assesses in detail the patient's movement patterns (computerised gait analysis). The gait analysis provides parameters of gait (step lengths, velocity and single limb support) that form objective, functional outcome measures. In addition, patients usually complete the Western Ontario and McMaster Universities Osteoarthritis (WOMAC) index (a disease-specific tool used for people with knee osteroarthritis to measure physical function, pain, and stiffness in the past 48 hours), the SF-36 (a widely used generic measure of health-related quality of life), and the Stopping Elderly Accidents Deaths and Injuries (STEADI) assessment (an assessment to evaluate the risk of falls). This can be done in a clinic or remotely using a smartphone application.

- Step 2: personalised device and treatment programme. After the initial assessment, the trained healthcare professional personalises the pair of AposHealth foot-worn devices by calibrating the under sole pods to the patient's needs and prescribes a personalised programme for the patient.

- Step 3: treatment. Patients wear the device for a short period during the day (see Table 1), while carrying out usual daily activities either at home or at work.

- Step 4: ongoing monitoring. Patients will undergo up to 4 follow-up consultations over the year. This includes a retest of their computerised gait analysis and questionnaires which were done during the initial consultation. Combined, these provide a decision-supporting tool to determine whether or not to change the device’s calibration or adjust the treatment plan. Follow ups are usually done face-to-face but may be done remotely.

Table 1 – Recommended daily time to wear AposHealth

Week number	Time spent wearing the AposHealth device per day	Time spent walking or standing in the AposHealth device per day
1	30 minutes	6 minutes
2	40 minutes	8 minutes
3	50 minutes	10 minutes
4	60 minutes	12 minutes

The outcome measures from the gait analysis and questionnaires are fed into the AposHealth clinical tracking system which processes them and can be graphically presented to the patient, presented to the referring health care provider, and used for assessment of effectiveness of treatment.

The company claims that the technology is the first home-based non-invasive treatment for people with knee osteoarthritis based on 2 biomechanical principles. The device improves biomechanics by redistributing pressure away from affected areas and thus reducing knee pain. On a neuromuscular level, it re-educates the muscles and can correct abnormal gait patterns, which can extend to when not actively wearing the footwear.

AposHealth is not suitable for people who have unexplained recurrent falls, people who experience balance problems and need indoor walking aids, and people with especially severe osteoporosis.

1.2 Relevant diseases and conditions

The scope of this evaluation is for using AposHealth for treating knee osteoarthritis. Knee osteoarthritis is the most common form of osteoarthritis. It typically presents with joint symptoms such as pain and stiffness. Symptoms vary from mild and intermittent, to more persistent or severe. The company

claims the device can treat hip, lower back, and ankle pain but this is not the focus of this scope.

Knee osteoarthritis is more common in women, people living in deprived areas, people aged 45 and over and people who are obese. It is estimated that 1 in 5 people over 45 years have knee osteoarthritis in England. The prevalence of osteoarthritis is increasing. Between 1 January 2018 to 30 December 2020, The National Joint Registry for England, Wales, Northern Ireland and the Isle of Man recorded 226,350 primary total knee replacements. Osteoarthritis was given as a documented indication for surgery in 97.4% of these cases.

1.3 Current management

Treatment of knee osteoarthritis depends on the severity of symptoms. Current treatment options include pharmacological and non-pharmacological treatments. NICE's guideline on the care and management of osteoarthritis recommends assessing the effect of osteoarthritis using a holistic approach. Healthcare professionals should ensure people with knee osteoarthritis have access to accurate verbal and written information.

Non-pharmacological treatment options include prescribed exercise to improve function and mobility, interventions to achieve weight loss for people who are obese or overweight, and devices (such as supports, splints, and braces) for people with biomechanical joint pain or instability. Healthcare professionals should consider the use of transcutaneous electrical nerve stimulation (TENS) as an adjunct to core treatments for pain relief.

Pharmacological treatment options include medications and corticosteroid injections to relieve pain and inflammation. However, these treatments may become less effective as the severity of knee osteoarthritis increases. Topical non-steroidal anti-inflammatory drugs and topical capsaicin should be considered as an adjunct to core treatments for pain relief. NICE's interventional procedures guidance on platelet-rich plasma injections for knee osteoarthritis states that this procedure should only be used with special arrangements for clinical governance, consent, and audit or research.

Referral for knee surgery should be considered for people who experience joint symptoms (pain, stiffness and reduced function) that have a substantial impact on their quality of life, and have been offered, or are refractory to, the core (non-surgical) treatment options. NICE's guideline on joint replacement (primary): hip, knee and shoulder recommends offering a choice of partial or total knee replacement to people with isolated medial compartmental osteoarthritis. Surgery may not be suitable for some people who are unable, or do not want to undergo surgery.

1.4 Regulatory status

AposHealth received a CE mark in October 2017 as a class IIa medical device for knee osteoarthritis.

1.5 Claimed benefits

The benefits to patients claimed by the company are:

- Improved quality of life due to reduced pain and improved joint function
- Reduced need for knee replacement surgery

The benefits to the healthcare system claimed by the company are:

- Cost savings as a result of reduced need for conventional therapies and associated appointment costs for physiotherapy, knee braces, orthotic devices, joint injections, and pharmacological treatments
- Increased operating and facilities resources due to reduced need for knee replacement surgery and associated post-operative hospital stay
- Reduced waiting lists for surgical treatments
- Increased patient compliance and engagement due to ease of use of the technology

2 Decision problem

Population	Adults aged 16 years and over with knee osteoarthritis who have been offered but not sufficiently benefited from non-surgical standard care treatment options, including education and advice; exercise and manual therapy; weight loss (for people who are overweight); and pain relief (oral, topical, or transdermal).
Intervention	AposHealth alone or in addition to non-surgical standard care
Comparator(s)	Non-surgical standard care treatment options, including but not limited to: • Devices (such as supports, splints and braces) • Intra-articular corticosteroid injections

Outcomes	The outcome measures to consider include:
	• measures of treatment effectiveness
	  ○ patient reported outcome measures (for example, the Western Ontario and McMaster Universities Osteoarthritis Index and the Oxford Knee Score)
	  ○ STEADI assessment
	  ○ mobility
	  ○ avoidance of knee replacement
	  ○ avoidance of secondary care referral
	  ○ health-related quality of life (for example, measured by the SF-36)
	• measures of resource use
	  ○ health care use (for example, use of corticosteroid injections, analgesic use, number of physiotherapy sessions, and other healthcare appointments)
	  ○ surgical intervention - knee replacement
	  ○ surgical intervention - other
	• device-related adverse events

Cost analysis	Costs will be considered from an NHS and personal social services perspective. The time horizon for the cost analysis will be long enough to reflect differences in costs and consequences between the technologies being compared. Sensitivity analysis will be undertaken to address uncertainties in the model parameters, which will include scenarios in which different numbers and combinations of devices are needed.
Subgroups to be considered	• People for whom knee replacement is recommended • People who do not want, or cannot have surgical intervention
Special considerations, including those related to equality	AposHealth is intended for people with knee osteoarthritis. The technology is contraindicated in people who have severe imbalance or vertigo issues. The technology is also not suitable for people considered at high risk of falls or those with severe osteoporosis. The technology should be worn for at least an

	hour a day so may not be suitable for people with very limited mobility or those who use walking aids to get around at home, depending on clinical judgment. Osteoarthritis is more common in people who are older, in women and in people with obesity. One meta-analysis conducted in North America found that pain severity and disability is higher for people with an African family background compared with people with a European family background. Age, sex, disability and race are protected characteristics.	
Special considerations, specifically related to equality	Are there any people with a protected characteristic for whom this device has a particularly disadvantageous impact or for whom this device will have a disproportionate impact on daily living, compared with people without that protected characteristic?	No
	Are there any changes that need to be considered in the scope to eliminate unlawful discrimination and to promote equality?	No
	Is there anything specific that needs to be done now to ensure the Medical Technologies Advisory Committee will have relevant information to consider equality issues when developing guidance?	No
Any other special considerations	Not applicable	

3 Related NICE guidance

Published

- Chronic pain (primary and secondary) in over 16s: assessment of all chronic pain and management of chronic primary pain (2021) NICE guideline NG193.
- Joint replacement (primary): hip, knee and shoulder (2020) NICE guideline NG157.
- Platelet-rich plasma injections for knee osteoarthritis (2019) NICE interventional procedures guidance IPG637.
- Osteoarthritis: care and management (2014) NICE guideline CG177 (currently being updated, publication expected October 2022.

In development

There is no related guidance in development for this technology.

4 External organisations

4.1 Professional

The following organisations have been asked to comment on the draft scope:

- Bedfordshire Clinical Commissioning Group
- British Orthopaedic Association
- British Society for Rheumatology
- Chartered Society of Physiotherapists
- Mid Essex Clinical Commissioning Group
- Primary Care Rheumatology Society
- South East London Clinical Commissioning Group

4.2 Patient

NICE's Public Involvement Programme contacted the following organisations for patient commentary and asked them to comment on the draft scope:

- Arthritis Action
- Arthritis and Musculoskeletal Alliance (ARMA)
- British Orthopaedic Association Patient Liaison Group
- Dystonia Society
- Lindsay Leg Club Foundation
- Versus Arthritis