NATIONAL INSTITUTE FOR HEALTH AND CARE EXCELLENCE

Diagnostics Assessment Programme

Devices for remote continuous monitoring of people with Parkinson's disease

Final scope

February 2022

1 Introduction

The Personal KinetiGraph (PKG) Movement Recording System is manufactured by Global Kinetics Corporation. The topic selection oversight panel identified the PKG as potentially suitable for evaluation by the Diagnostics Assessment Programme based on a NICE medtech innovation briefing on the PKG for remote clinical management of Parkinson's disease published in May 2021.

The revised scope was informed by discussions at the scoping workshop on 6 January 2022 and the assessment subgroup meeting held on 18 January 2022. A glossary of terms and a list of abbreviations are provided in appendices A and B.

2 Description of the technologies

This section describes the properties of the technologies based on information provided to NICE by manufacturers and experts, and information available in the public domain. NICE has not carried out an independent evaluation of this description.

2.1 Purpose of the medical technologies

People with Parkinson's disease experience a range of motor symptoms, which can fluctuate in severity during the day and between days. Starting or adjusting treatment helps to control these symptoms. However, these treatments can themselves cause motor-related side effects. An important consideration in decisions about treatment is the need to balance the benefits of treatment with the potential side effects. Current practice for monitoring the motor symptoms of people with Parkinson's disease includes using validated questionnaires, history-taking and clinical observation. It can be difficult to assess the symptoms of people with Parkinson's disease who have difficulty

communicating, recalling or recording their symptoms. Examination at a single point in time may over- or underestimate symptom severity or incidence, given that motor fluctuations can vary over time. Devices that can monitor and record motor symptoms such as dyskinesia (involuntary movement), bradykinesia (slowness) and tremor over several days could identify people who could benefit from changes to their care who might otherwise be missed. Assessing movement at night may also help identify sleep related issues such as sleep fragmentation (interrupted sleep), which could be caused by symptoms returning when medications wear off or night-time urination. In addition, episodes of immobility during the day may indicate daytime sleepiness and can help inform medication decisions.

Better informed treatment decisions could lead to an improvement in quality of life. A reduction in motor symptoms could also reduce falls and hip fractures. The technology could also help improve communication between people with Parkinson's disease and clinicians when discussing symptoms and potential changes to care.

The technology may also facilitate remote monitoring of people with Parkinson's disease. This could help to alleviate the stress and anxiety of attending clinical appointments. Measurement of symptoms could also reduce the length of clinical appointments and reduce the number of clinical appointments, thereby freeing up NHS resources.

The following technologies have been identified as relevant for this assessment because they have remote monitoring capability, are passive monitors, measure dyskinesia, help assess bradykinesia and can be used outside a clinical setting in the absence of a health professional. Tremor was also noted as an important feature to assess because it can be indicative of how well a person is responding to medication.

2.2 Product properties

The level of detail in the following descriptions depends on the extent of information provided by manufacturers during topic scoping. Technologies will only be included in guidance if they are available to the NHS and have appropriate regulatory approval.

2.2.1 The Personal KinetiGraph (PKG) Movement Recording System (Global Kinetics Corporation)

The PKG Movement Recording System (Global Kinetics Corporation) is a Class IIa CE-marked system that uses a PKG Watch that continuously measures movement. It is intended to quantify kinematics (body motion) of

movement disorder symptoms in conditions such as Parkinson's disease, including tremor, bradykinesia and dyskinesia. It has event markers for medication reminders and patient acknowledgement. It is also intended to be used to monitor activity associated with movement during sleep. The manufacturer states that PKG is an adjunct to clinical practice and should be used in combination with patient and healthcare consultation. They envisage that the PKG is used twice a year.

Healthcare professionals can order the PKG online. The manufacturer then sends the watch directly to the person who will wear it (for a period of 6 days), also providing a paid, addressed envelope for the watch to be returned to the manufacturer. Data is then extracted and processed by cloud-based algorithms and a report is generated for the healthcare professional to view online.

The PKG measures bradykinesia, dyskinesia, tremors, motor fluctuations, immobility and is able to identify when the watch is not being worn. It can also prompt the user to take their medication at prescribed times and the user can register when they have taken their medication. As well as providing the raw data, it can generate a report based on movement over a 6-day period using validated proprietary algorithms. The report includes summary graphs showing measurements over time and provides the following scores with suggested target ranges or interpretation:

- A bradykinesia score
- A dyskinesia score
- A fluctuation dyskinesia score
- Percentage of time with tremor
- Percentage of time immobile (indicative of daytime sleepiness)

The manufacturer has stated that new versions of the technology will include 24-hour measurements of sleep-related functions. The device is intended to be interpreted only by trained technicians or clinicians, and as an aid to existing clinical methods. It is not intended to be the sole or primary means of clinical assessment. The PKG is not recommended for people with Parkinson's disease who have restricted movement (for example, confined to bed) or for people who operate heavy machinery for prolonged periods. The manufacturer offers a "fulfilment service" to help educate people on how to activate and wear the PKG watch. An email address and phone number are provided for on-hand technical advice to support the user.

The manufacturer provides healthcare professionals with education and training, and state that healthcare professionals should interpret an average of

15 to 20 PKGs to be proficient, supported by an eLearning module, which takes approximately 1 to 2 hours. The person wearing the watch receives a product insert detailing instructions of how to use the PKG.

2.2.2 STAT-ON (Sense4care)

The STAT-ON is a Class IIa CE-marked, waist-worn inertia recorder, configured by a doctor for use in clinical, ambulatory or home environments. It measures motor disorders and events when worn by someone with Parkinson's disease, but does not measure tremor. The device measures dyskinesia, 'on' and 'off' periods, gait parameters (including bradykinesia and freezing of gait), falls, energy expenditure and posture. It can also register when medication has been taken and up to 10 alarms per day can be set.

Only health professionals should manage use of the device. Health professionals should provide the sensor to the user correctly configured and charged. Results can be used to adjust or evaluate a therapy or to adjust a person's diet.

The STAT-ON system consists of a monitoring device, its base charger, a belt, and a mobile application. The device collects data and uses artificial intelligence algorithms to process it. Results are stored in its internal memory. The smartphone application connects to the STAT-ON device via Bluetooth. The app is used for configuring the system and for downloading the data. It also sends the data as a report by email.

The manufacturer has advised that the STAT-ON could be worn during the night to monitor movement. The user should wear the system for a minimum of 5 days (ideally for 7 days), totalling a minimum of 24 hours over the 5 days to generate enough data. After this, a report can be generated at any time. A health professional can download the report to their phone using the STAT-ON application which automatically generates a report of the motor state and symptoms during time of use.

Reports include a summary of activity and the prevalence of symptoms during the monitored period, including:

- Total freezing of gait episodes and average number of episodes per day
- Average minutes walking and number of steps per day
- Number of falls
- Time in 'Off'/ Intermediate/ 'On'
- Time with dyskinesias.

As well as numerically, data is also presented in graphs. In addition to a summary report, a more detailed report with further data analysis can also be produced.

The STAT-ON device is not indicated for children or for people with Parkinson's' disease with Hoehn & Yahr Scale 5. The device should not be worn by a person in a wheelchair or using crutches as the results will not be valid.

2.2.3 Kinesia 360 (Great Lakes Neurotechnologies)

The Kinesia 360 is intended to monitor physical motion and muscle activity to quantify movement disorder symptoms and assess activity in any instance where quantifiable analysis of motion and muscle activity is desired. The system provides remote, continuous measurement of symptoms.

The Kinesia 360 kit consists of a tablet, sensors and charge pad, USB cable and charge pad power cable. Sensors worn on the wrist and ankle combined with a mobile application continuously record data, including dyskinesia and tremor. The sensors record data all day and recharge overnight for extended home use. The mobile application also includes electronic diaries for capturing patient-reported outcomes and customizable medication diaries.

When the Kinesia Sensor bands are returned to the charging pad, data from the motion sensors is automatically downloaded and then uploaded to the Kinesia Web Portal, and algorithms are used to detect symptoms and calculate severity scores. Clinicians can view web-based reports that include:

- A dyskinesia score
- Total and percentage of time with tremor
- Total and percentage of time at rest
- Total and percentage of active time (but not walking)
- Number of steps
- A symptom summary report that displays how tremor, slowness, dyskinesia and walking change over time.
- A dose report that shows how tremor, slowness, dyskinesia and walking change as a function of different medication or therapy does.

The Kinesia 360 has a Class I CE-mark and is available for sale in the UK.

2.2.4 KinesiaU (Great Lakes Neurotechnologies)

The KinesiaU measures tremor, slowness and dyskinesia using a smartwatch and smartphone application. Patients can view reports in real-time and share these with their healthcare professionals. The product is to be used only under the direction of a qualified clinician and all changes to therapy regimens are to be based solely on the clinical judgment of the clinician.

The reports rates the severity of tremor, slowness, and dyskinesia symptoms into good, mild, moderate and severe categories. This can be measured through specific active tasks or through continuous recording. To start a continuous (all day) recording, the user must tap the Continuous button on the home screen. The smartwatch app must be kept open during the recording. Active tasks may be performed during the continuous recording.

Reports can be produced throughout the day and over the course of days, weeks, and months in response to therapy and activities. The report page on the smartwatch app displays the severity of the selected symptom (tremor, slowness and dyskinesia) averaged for the selected time range. The symptoms can be displayed individually or averaged together and shown as “All symptoms”. The mobile application also includes customizable medication and exercise diaries, which can be added to the report. Patients can view reports in real-time and share reports (pdf format) with their healthcare professionals.

The KinesiaU currently has FDA approval, and the manufacturers are seeking CE-marking.

2.2.5 PDMonitor (PD Neurotechnology)

The PDMonitor system measures activity/posture, bradykinesia, freezing of gait, gait disturbances, wrist tremor, leg tremor, dyskinesia and on and off periods. The system has a Class IIa CE-mark.

The duration and frequency for which the person wears the device is decided by the physician. The device should be removed when performing intense fitness activities.

The PDMonitor system consists of the SmartBox, 5 monitoring devices and a PDMonitor mobile application. The devices are worn on both wrists, ankles and one is worn on the waist, and acquire movement data for assessing motor symptoms. The PDMonitor SmartBox is a docking station for charging the monitoring devices, collecting, storing and processing data and uploading them to the PD Neurotechnology storage service. The SmartBox must be connected to the PD Neurotechnology storage service to be properly

configured either via an ethernet cable or an available Wi-Fi network. This requires an internet connection. A web-based application can be used by healthcare professionals to view and download patient reports. The PDMonitor mobile application is an electronic diary for medications, diet and symptoms related to Parkinson's disease. It also provides a summary of daily activity as recorded by the PDMonitor system.

3 Target conditions

3.1 Parkinson's disease

Parkinson's disease is a condition that affects the brain, resulting in a progressive loss of coordination and movement problems. It is caused by a loss of cells in the brain that are responsible for producing dopamine, which helps to control and coordinate body movements. In the early stages of Parkinson's disease, the 3 main symptoms are shaking (tremor), slowness of movement (bradykinesia) and muscle stiffness (rigidity). These develop gradually, in no particular order (NHS Parkinson's disease). Other physical symptoms that can occur early on include balance problems, nerve pain and sleep disturbances.

The Parkinson's UK website explains that healthcare professionals often refer to different 'stages' of Parkinson's. Early or diagnosis stage describes the period when someone is first experiencing symptoms, being diagnosed and then coming to terms with this. The maintenance phase is used to describe when a person's symptoms are controlled, perhaps by medication. People with advanced Parkinson's disease or in the complex phase of Parkinson's disease, have more complicated symptoms that significantly impact daily living, including anxiety, depression and dementia. Advanced Parkinson's disease has a severe negative impact on the quality of life of patients, their families and carers. The palliative stage involves providing relief from the symptoms, stress and pain of the condition (Parkinson's UK).

The Parkinson's UK report on the incidence and prevalence of Parkinson's states there are around 137,000 people living with Parkinson's disease in the UK. Men are more likely to develop Parkinson's disease than women, and the risk of developing the disease increases sharply with age. It is estimated that around 10% of patients have advanced disease (NHS England). In 2018 there were 6,505 deaths due to Parkinson's disease in England and Wales. All deaths occurred in people aged 50 or above, with 87% occurring in people aged over 75 years or above (Office for National Statistics).

Levodopa treatment (used for management of motor symptoms; see section 3.2.2) is associated with motor complications, including response fluctuations

and dyskinesias (involuntary movements) and ‘wearing off’ of the drug or ‘end-of-dose’ deterioration with progressively shorter duration of benefit occurring over time. Response fluctuations are characterised by large variations in motor performance, with normal function during the ‘on’ period, and weakness and restricted mobility during the ‘off’ period.

Sleep disturbances such as insomnia, nocturia (night time urination) and restless leg syndrome (‘jumping’ of the legs or arms) can be caused by ‘wearing-off’ periods during the night.

Dopaminergic therapies can also cause non-motor side-effects such as impulse control disorders, excessive sleepiness or sudden onset of sleep and psychotic symptoms such as hallucinations and delusions.

3.2 Diagnostic and care pathway

3.2.1 Current methods of assessing and monitoring of motor symptoms

Clinical experts highlighted that people with confirmed Parkinson’s disease are referred to Parkinson’s nurse specialists or geriatricians within 6 to 8 weeks of diagnosis. The NICE guidelines for Parkinson’s disease (NG71) recommends that before starting treatment for people with Parkinson’s disease, the following are discussed:

- the person's individual clinical circumstances, for example, their symptoms, comorbidities and risks from polypharmacy
- the person's individual lifestyle circumstances, preferences, needs and goals
- the potential benefits and harms of the different drug classes.

Clinical experts commented that in the NHS people with Parkinson’s disease typically have review appointments (in-person at home or in a secondary clinical setting or remotely) every 3 to 12 months to review their condition. The NICE guideline for Parkinson’s disease (NG71) recommends that people diagnosed with Parkinson's disease should be seen at regular intervals of 6 to 12 months to review their diagnosis. The guideline further states that once treatment is commenced, follow-up may need to be more frequent (every 2 to 3 months) to assess the response to medication, titrate dosage and re-visit the diagnosis. In later disease, people with Parkinson’s disease have more complex problems which require changes in medication. This may require review at frequent intervals (every 2 to 3 months). Clinical experts highlighted that review frequency is based on a person’s needs and situation and can be more frequent than every 2 to 3 months if needed, for example to monitor

treatment response, especially for monitoring therapies for advanced Parkinson's disease, or if a patient reports issues. However, pressures on services, exacerbated by the COVID-19 pandemic, have impacted on how often appointments can be provided. The pandemic has also led to greater use of remote appointments.

A person's motor symptoms are assessed through patient or carer-reported history taking, for example diaries, and different questionnaires which may be sent to the person ahead of the review or administered during the review. The Movement Disorders Society (MDS) recommends nine rating scales for assessing motor symptoms. Selection of the most appropriate instrument for a particular objective requires consideration of the characteristics of each scale and the goals of the assessment. Clinical experts commented that in NHS practice the MDS Unified Parkinson's Disease Rating Scale (UPDRS) – part 2, the Modified Bradykinesia Rating Scale (MBRS) and the Hoehn and Yahr scale are the most frequently used, although noting that there often was not time to complete these tools in full. Some experts highlighted that questionnaires were sent ahead of review appointments. Some people may also choose to use mobile applications for measuring activity to support their personal diaries.

Clinical experts highlighted the importance of taking a good sleep history to assess the potential impact of symptoms on sleep, and that this was often supported by sleep diaries. Some questionnaires used (as described above) may also pick up issues related to sleep.

3.2.2 Treatment

Recommendations for the treatment of Parkinson's disease are outlined in the NICE guideline for Parkinson's disease in adults (NG71). All patients should be offered both non-pharmacological and pharmacological management for motor symptoms. These include referral to a physiotherapist for physical activity regimes. This can also include referral to an occupational therapist for people with difficulties doing day-to-day activities.

Levodopa is recommended as the first-line treatment for people in the early stages of Parkinson's disease whose motor symptoms impact their quality of life. Clinical experts highlighted that a monoamine oxidase Type B (MAO-B) inhibitor may be offered if a patient prefers to delay treatment with levodopa. For people with symptoms that do not impact on quality of life, dopamine agonists, levodopa or monoamine oxidase B (MAO-B) inhibitors may be offered.

People having long-term levodopa treatment develop motor complications. These include motor fluctuations, where the patient switches between being able to move ('on' period) and being immobile ('off' period), and involuntary movements (dyskinesias). The British National Formulary states that modified-release preparations may help with 'end-of-dose' deterioration or nocturnal immobility. Clinical experts stated that the dose and timing of levodopa can be adjusted to prolong or shift "on" periods.

Dopamine agonists, monoamine oxidase Type B (MAO-B) inhibitors or catechol O methyl transferase (COMT) inhibitors are offered as additional treatment for people who have developed dyskinesia or motor fluctuations despite optimal levodopa therapy. If the dyskinesia remains uncontrolled, amantadine can be considered. A clinical expert commented that amantadine may be less likely to be used for older people or because it can cause confusion.

Advanced Parkinson's disease

The NICE guideline for Parkinson's disease in adults also includes recommendations specific to advanced Parkinson's disease. The symptoms of advanced Parkinson's disease may still be responsive to adjustments in the dose and combination of levodopa with adjuvant MAO-B and/or COMT therapies (Ferreira et al., 2013). Device-assisted therapies are offered to people with advanced Parkinson's disease. Intermittent apomorphine injection and/or continuous apomorphine infusion may also be considered. Deep brain stimulation (DBS) can be considered in people with late-stage Parkinson's disease whose symptoms do not respond adequately to best medical therapy. Clinical experts highlighted that this procedure is only normally considered for people who have been taking medication for Parkinson's disease for over 5 years.

Levodopa–carbidopa intestinal gel is another device-assisted therapy, it is currently available through an NHS England clinical commissioning policy. It can be considered in certain people with advanced levodopa-responsive Parkinson's disease, with severe motor fluctuations that have not responded to available medications. NICE recommended that this policy is reviewed in light of NG71 (NICE guidelines for Parkinson's disease in adults, section 1.8.4). Clinical experts highlighted that this treatment is rarely used within the NHS in England, it is only used for patients who fulfil very strict inclusion criteria, as defined in the NHS England clinical commissioning policy.

Sleep disorders

The NICE guideline for Parkinson's disease recommends adjusting medicines to reduce the occurrence of daytime sleepiness or sudden onset of sleep,

having first sought advice from a healthcare professional with specialist expertise in Parkinson's disease. The guideline also recommends that use of modafinil should be considered to treat excessive daytime sleepiness in people with Parkinson's disease if a detailed sleep history has excluded reversible pharmacological and physical causes. Modafinil is contraindicated in people who are pregnant or who are planning a pregnancy. People with Parkinson's disease who are taking modafinil should be reviewed at least every 12 months by a healthcare professional with specialist expertise in Parkinson's disease.

The guideline also recommends that for people with Parkinson's disease and sleep disturbance to take care to identify and manage restless leg syndrome and rapid eye movement sleep behaviour disorder. Clonazepam or melatonin may be considered to treat rapid eye movement sleep behaviour disorder if a medicines review has addressed possible pharmacological causes. For people with nocturnal akinesia (loss of ability to move), levodopa or oral dopamine-receptor agonists should be considered as first-line options and rotigotine as second-line (if both levodopa or oral dopamine-receptor agonists are ineffective).

3.3 Patient issues and preferences

Patient preferences are key to treatment decisions. Clinical experts highlighted the importance of shared decision making. The benefits of treatment must be balanced against the potential side-effects (for example, dyskinesia). The technologies may identify worsening symptoms in people with Parkinson's disease, but the individual might not consider them severe enough to make changes in their medication. The person's occupation, lifestyle and preference for non-oral therapies are also considered when prescribing medication. People may also value the ability to track symptoms over their lifetime once diagnosed with Parkinson's disease.

Clinical experts commented that the technologies may help improve communication between people with Parkinson's disease and health professionals by offering objective evidence of the state of their symptoms. This will particularly be the case for people who struggle to subjectively assess improvements or deterioration of their symptoms.

If allowing more remote appointments, the technologies may reduce costs to people with Parkinson's disease, and their carers, associated with travelling to an in-person appointment (such as travel and parking). Reducing the need to go to hospital for appointments could help to reduce medicalisation of a Parkinson's disease diagnosis.

Ensuring that any results generated by technologies are communicated in a timely manner and well explained was also highlighted as an important issue.

4 Position of the technologies in the care pathway for assessment

Clinical experts commented that the technologies would be used alongside current assessment but noted that they could be used in different ways. This could be use alongside current practice when people have review appointments (in-person or remotely), for example every 3 to 12 months.

Alternatively, the technologies may only be used in particular circumstances when use is considered particularly beneficial to help decisions about care, such as:

- If motor fluctuations are not being adequately managed
- If response to treatment is unclear, for example if there is uncertainty about the severity of symptoms
- To inform use of device-assisted therapies such as deep brain stimulation.

Clinical experts also commented that use of the technologies could enable greater use of remote appointments, but highlighted that contact with healthcare professionals would still be needed for some assessments, for example to take blood pressure readings, assess cognition and to perform mood assessments.

The technologies could also be used without a review appointment, that is, generated results being considered by healthcare professional without an appointment with the person with Parkinson's disease, for example when a person indicates they are having problems with symptoms. NHS experience of this type of use is described in Dominey et al.,(2020) based on use in the University Hospitals Plymouth NHS Trust between July 2015 and January 2018. The PKG was offered to people who were willing to wear the device, living at home and normally ambulant, without significant comorbidities impacting mobility. For newly diagnosed patients the PKG was offered at 6 months to facilitate treatment titration between the 4 and 12 month visits. For follow-up patients the PKG was offered 3 to 6 months after their last clinic appointment, to facilitate treatment titration prior to their next in-clinic review at 12 to 18 months.

An alternative approach to this is now in use within the Plymouth Hospitals NHS Trust where the PKG is used in place of review appointments, that is, no

review appointments are scheduled and the PKG is used to inform decisions about when these are needed. In this pathway, validated questionnaires are sent to the patient alongside the PKG. The PKG report is used to form recommendations for further care, which is communicated to the person with Parkinson's disease and the Parkinson's disease nurse specialist. An appointment to decide on changes to medication can then be arranged if the PKG report indicates this may be beneficial.

Current treatment and options for changing this (for example, to add a further treatment or change dosage) will change as a person's condition progresses. The decisions about care that the technologies will contribute to will therefore vary by stage of condition (see section 3.1); for example, people with advanced Parkinson's disease will have different treatment options such as device assisted therapies.

5 Comparator

The assessment of Parkinson's disease symptoms in current clinical practice varies. It includes history taking, patient reported diaries and use of the UPDRS, Hoehn and Yahr, and MBRS scales. The use of the questionnaires may vary in clinical practice. People may also use technologies such as mobile activity trackers or step counters to support information recorded in personal diaries.

6 Scope of the assessment

Table 1 Scope of the assessment

Decision question	Do devices for remote continuous monitoring of people with Parkinson's disease represent a clinically and cost-effective use of NHS resources?
Populations	People with Parkinson's disease Where data permits, the following subgroups may be considered: • Based on current treatment and treatment options • People with advanced Parkinson's disease • People with communication barriers • Based on ethnicity
Interventions	The Personal KinetiGraph (PKG) Movement Recording System, Kinesia 360, Kinesia U, STAT-ON or PDMonitor used in addition to current care for monitoring motor and non-motor symptoms, when used: • for all review appointments,

	• for a subset of review appointments (see section 4), or • without a review appointment (that is, generated results being considered by a healthcare professional without an appointment with the person with Parkinson's disease; see section 4)
Comparator	Assessment of motor and non-motor symptoms using clinical judgement (based on information including clinical history and patient diaries), which may include use of rating scale tools and activity trackers
Healthcare setting	Community or secondary healthcare setting
Outcomes	Intermediate measures for consideration may include: • Impact on clinical decision-making (including potential changes to therapy identified which were contraindicated or declined by the patient) • Performance to measure motor and non-motor symptoms of Parkinson's disease • Number and length of clinical appointments • Number and length of hospital admissions • Number and frequency (incidence) of remote appointments • Use of interventions (including pharmacological and non-pharmacological interventions for management of motor and non-motor symptoms associated with Parkinson's disease) • 'On'/'off' periods • Ease of use/acceptability by clinicians • Adherence to taking medicines
	Clinical outcomes for consideration may include: • Morbidity (including falls, hip fracture, disease severity, dyskinesia, bradykinesia, tremor, cognitive functioning, non-motor outcomes, sleeping patterns, adverse effects of treatment and incidence of motor symptoms) • Mortality
	Patient- and carer-reported outcomes for consideration may include: • Health-related quality of life • Ease of use and acceptability for patients and carers • Patient and carer experience (including quality of care, patient and carer satisfaction and engagement- for example, impact on discussions about symptoms

	management, communication and relationship between patients and clinicians)
	Costs will be considered from an NHS and Personal Social Services perspective. Costs for consideration may include: • Costs related to using intervention (including any time analysing and storing data, communicating results and arranging for use of the technology) • Cost of training for staff to interpret results and for users of the device to operate it • Cost of review appointments • Cost of further tests • Cost of treatment (including costs of any adverse events)
	The cost-effectiveness of interventions should be expressed in terms of incremental cost per quality-adjusted life year.
Time horizon	The time horizon for estimating clinical and cost effectiveness should be sufficiently long to reflect any differences in costs or outcomes between the technologies being compared.

7 Other issues for consideration

7.1 Limitations

Clinical experts highlighted that the technologies may not be suitable for people with severe cognitive impairment, Alzheimer's disease or people with impulse disorders. This is because they can require user input to measure medical compliance, so may cause stress and anxiety in these patients, unless a carer can assist with this. Clinical experts also highlighted the value of the technologies may be limited in people who are extremely frail or whose symptoms are mostly restricted to their lower limbs (for wrist-worn devices).

7.2 Carer Considerations

Any impact of the technologies on people with Parkinson's disease will also affect their carers. This assessment should also take into account impact on carers, where possible.

7.3 Environmental considerations

A clinical expert highlighted if the technologies reduced the number of face-to-face appointments, they could offer a more environmentally sustainable pathways by reducing the amount of travel associated with patients visiting healthcare facilities and with healthcare professionals visiting patients.

8 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.

Parkinson's disease predominantly affects older people and is more common in men than women. Many people with Parkinson's disease may be protected under the disability provision of the Equality Act because their condition is likely to have long-term adverse effects on their ability to do normal day-to-day activities. People who are frail or have cognitive impairment or both may struggle to use the technology. The technology is not suitable, or may not work as well, for people who have restricted movement, for example people who are bed bound or wheelchair users.

People with Parkinson's disease from the black, Asian and minority ethnic community may have an atypical pattern of Parkinson's disease that is not often recognised by healthcare professionals (NICE MIB258). Recent findings from a UK study suggest differences in the phenotype of Parkinson's disease in people from a black, Asian or other minority ethnic group, with a greater burden of non-motor symptoms, motor disability and a higher rate of cardiovascular comorbidities (Sauerbier et al., 2021). Incidence of Parkinson's disease may vary by ethnicity.

Clinical experts highlighted that this technology may offer additional value to people experiencing problems communicating their symptoms. This may include people with language barriers, people with recall problems and people who live alone who may not notice changes in their symptoms. This could benefit people with cognitive disorders and people who do not speak English as a first language. An expert warned that the technology should not replace high-quality interpreters.

Clinical experts highlighted importance of accessibly of training and other user-support resources for people with hearing loss or visual impairment.

Improved remote management of Parkinson's disease may improve health outcomes for people in more rural or remote settings. Wider availability of remote appointments may also allow greater access to care for people who are less able to afford travel to in-person appointments.

9 Potential implementation issues

The PKG is currently in routine use in several NHS acute trusts. It is not clear whether the other technologies are currently in use. Few barriers to adoption were identified if NICE recommended use of the technologies, beyond cost.

9.1.1 Increased administration

Despite not raising concerns about anticipated need for increased capacity or appointment time when using the technologies, clinical experts highlighted that there may be a need for additional time to order the technologies and to navigate internal IT systems. Clinical experts highlighted that the ease with which data or reports generated by the devices could be integrated into existing patient data systems could be a barrier to implementation.

9.1.2 Training

Some users of the PKG highlighted that it was important to ensure that the person interpreting the results was suitably supervised until they had gained sufficient competence in understanding the report generated. Ensuring that a suitable level of expertise is maintained for all users, particularly where clinicians may only see a small number of reports each year, was also highlighted as important.

9.1.3 Optimal use of the technology

Experts raised uncertainty about the best time to use the technologies. Currently, the frequency of use of the technology varies between technologies.

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Appendix A Glossary of terms

Bradykinesia
Slowness of movement. A diagnosis of Parkinson's disease is considered when bradykinesia plus either tremor or rigidity is present.

Dyskinesia
Dyskinesias are involuntary, erratic, writhing movements of the face, arms, legs or trunk.

Tremor
Tremor tends to occur in the hands and is often described as "pill-rolling". But it can also appear in other parts of the body, including the lower lip, jaw or leg. Some people report an internal tremor, a shaking sensation inside the chest, abdomen or limbs that cannot be seen.

Dystonia
Dystonia is a sustained or repetitive muscle twisting, spasm or cramp that can occur at different times of day and in different stages of Parkinson's disease.

Gait
A gait is a pattern of limb movements made during walking.

Hoehn and Yahr scale
The Hoehn and Yahr scale describes five stages of Parkinson's Disease progression.

Akinesia
Akinesia is the loss of ability to move muscles voluntarily.

Appendix B Abbreviations

PKG	Personal KinetiGraph
MDS	Movement Disorder Society
UPDRS	Unified Parkinson’s Disease Rating Scale
MBRS	Modified Bradykinesia Rating Scale
MAO-B	Monoamine oxidase B (MAO-B)
COMT	Catechol O methyl transferase

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