Anthem

Medical Policy

Subject: Physiologic Recording of Tremor using Accelerometer(s) and Gyroscope(s)
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Description/Scope

This document addresses a type of tremor analysis device that includes an accelerometer and a gyroscope. These devices are proposed for use in diagnosing tremor, in the management of individuals with implanted deep brain stimulation devices to guide adjustments to the neurostimulator settings, and other indications.

For information on additional testing, see:

- CG-ANC-08 Mobile Device-Based Health Management Applications
- CG-MED-24 Electromyography and Nerve Conduction Studies
- MED.00092 Automated Nerve Conduction Testing

Position Statement

Investigational and Not Medically Necessary:

The use of accelerometer/motion analysis testing devices is considered**investigational and not medically necessary** for all applications, including, but not limited to, the evaluation of tremors.

Rationale

A few small studies have investigated the clinical utility of accelerometric measurements for evaluation of tremor and functional ability in dyskinetic conditions, such as Parkinson's disease and stroke. The results, to date, have demonstrated inconsistent conclusions, and the authors acknowledge the need for further study to elucidate the clinical utility of these test devices and which population groups would potentially benefit from their use (Boroojerdi, 2019; Cheung, 2011; Gebruers, 2010; Perez Lloret, 2010).

Several studies have investigated the use of smartphone-based remote monitoring technology with the use of accelerometer and gyroscope data to assess tremors.

In 2017, Zheng and colleagues published a study with the aim to use a smartwatch with a triaxial accelerometer, a smartphone, and a remote server to quantify tremor objectively during daily activities. The study enrolled 9 participants, but 1 participant's data was lost. The remaining 8 participants each had an average effective data collection time of 26 hours. Despite scattered data points, the authors calculated significant correlation between the participants' Fahn-Tolosa-Marin Tremor Rating Scale (FTMTRS) self-assessment scores and the device ($r=0.84$, $p<0.001$); the device's qualitative measurements and the participants' self-assessment scores ($r=0.97$, $p=0.032$); the device's qualitative measurements and the neurologists' standardized assessment scores ($r=0.80$, $p=0.005$); and the neurologists FTMTRS and participants' FTMTRS mean auto-assessment scores ($r=0.84$, $p=0.009$). While this study had significant results, there were several limitations including small sample size, lack of control group or blinding, and incomplete data collection.

Lipsmeier and colleagues reported on the data of two independent smartphone-based remote monitoring studies (2018). One study was a 6-month phase 1b clinical drug trial with 44 individuals with Parkinson's disease. The other was a 6-week observational study of 35 age- and sex-matched healthy controls. Individuals received a smartphone with a mobile application pre-installed and a belt with a pouch in which to carry the smartphone. After training on the use of the smartphone and mobile application, individuals were instructed to complete six daily active tests (sustained phonation, rest tremor, postural tremor, finger-tapping, balance, and gait), then carry the smartphone throughout the remainder of the day for passive monitoring of daily activities, and lastly, charge the smartphone overnight. Once quality control was performed on the data collected, 15% of sustained phonation data (phonation not sustained for an adequate period) and 3% of all other active test data (for example, no walking during balance test) were removed. The data showed the individuals with Parkinson's disease completed 5135 active tests, which resulted in an average daily test completion of 3.5 out of 7 days per week and 61% of all possible test sessions. Active test features demonstrated moderate-to-excellent test-retest reliability (average intraclass correlation coefficient=0.84). A significant difference was found by all active tests and passive monitoring features in differentiating individuals with Parkinson's disease from healthy controls ($p<0.005$). Except for sustained phonation, all active tests were significantly related to the corresponding International Parkinson and Movement Disorder Society–Sponsored UPDRS clinical severity ratings (rest tremor, postural tremor, finger tapping, gait task: $p<0.05$; balance task: $p<0.01$). The authors stated, "On passive monitoring, time spent walking had a significant ($p=0.005$) relationship with average postural instability and gait disturbance scores." This study had several significant findings; however, there were also several limitations. First, intraclass correlation coefficients were calculated with mean data rather than individual data, which may have led to falsely higher values. And second, the data used was extracted from two separate studies with different study designs.

In 2018, Mehrang and colleagues released the results of a retrospective data analysis of age- and gender-matched individuals with Parkinson's disease (n=616) and controls (n=621). These individuals were part of the first phase of the larger mPower study conducted in 2015. All individuals were recruited remotely through their smartphones and inclusion criteria was very broad including being at least 18 years of age or older, in the United States, and proficient at reading and writing on the smartphone in English. The mPower study required individuals to participate in four different tests aimed to assess physical and mental abilities. One of the tests was a gait assessment test in which individuals had to walk 20 steps in a straight line while carrying their smartphone in their pocket or bag. Those individuals who completed at least one walking test and answered whether or not they had Parkinson's disease were age- and gender-matched using background data provided through the mPower study. The investigators found the accuracy, sensitivity, and specificity were all equal 0.7, which showed that individuals with Parkinson's disease could be differentiated from those without Parkinson's disease through the 20-step walking test. A major limitation to this study due to the retrospective design was the lack of data collected. Additionally, there was no information on the medications the individuals were taking, other diseases that could have impacted gait, or disease severity of Parkinson's disease.

Additional studies have investigated the clinical validity of accelerometric measurements to evaluate physical activity and gait variables in the elderly and in those with hip osteoarthritis using differing devices and methods of data analysis and reporting. The

authors acknowledged the need for further research to standardize testing methods and data reporting that compare devices in clinical practice (Bento, 2012; Item-Glatthorn, 2012). There is a lack of published evidence evaluating the clinical utility of accelerometers as compared to conventional testing modalities.

Background/Overview

There are multiple types of motion analysis accelerometers on the market for various applications including evaluation of physical exercise, weight reduction progress, and motion disorders, associated with certain conditions, such as Parkinson's disease. These devices attach to the individual's arm and other body parts to measure body motion. Once attached, the person is then asked to do several tasks, such as resting with their hands in their lap for several seconds, holding their arms straight out in front of them for several seconds, or extending their arm and touching their nose. Some models of these devices also include an electromyography (EMG) testing component.

One such device is the Kinesia™ (Great Lakes NeuroTechnologies, Cleveland, OH) which obtained clearance from the U.S. Food and Drug Administration (FDA) on April 6, 2007 through the 510(k) approval process. The Kinesia device is indicated to:

- monitor physical motion and muscle activity to quantify the kinematics of movement disorder symptoms, such as tremor; and
- assess activity in any instance where quantifiable analysis of motion and muscle activity is desired (FDA, 2007).

As technology has evolved, accelerometers and gyroscopes have been incorporated into smartphones and smartwatches, which allows analysis of motion through mobile applications. Performance of various tests, such as sitting to assess tremors and walking to assess balance and gait, while wearing such devices has been proposed as a method of testing for and managing tremor-related conditions.

Definitions

Accelerometer: A device that measures the change in position by detecting variations in motion or acceleration.

Clinical utility: An assessment of the risks and benefits resulting from using a particular test and the likelihood that the test will lead to an improved overall outcome.

Clinical validity: The accuracy with which a test identifies or predicts an individual's clinical status.

Gyroscope: A device composed of a spinning disc or light mechanism in a static frame. This type of device uses the principle of conservation of angular momentum to measure or detect changes in orientation and angular velocity.

Kinematics: A branch of physics that deals with aspects of motion apart from considerations of mass and force.

Coding

The following codes for treatments and procedures applicable to this document are included below for informational purposes. Inclusion or exclusion of a procedure, diagnosis or device code(s) does not constitute or imply member coverage or provider reimbursement policy. Please refer to the member's contract benefits in effect at the time of service to determine coverage or non-coverage of these services as it applies to an individual member.

When services are Investigational and Not Medically Necessary:

CPT	
95999	Unlisted neurological or neuromuscular diagnostic procedure [when specified as motion analysis testing using accelerometer(s) and/or gyroscope(s) (including frequency and amplitude), including interpretation and report, or continuous recording of movement disorder symptoms, including bradykinesia, dyskinesia and tremor]
0778T	Surface mechanomyography (sMMG) with concurrent application of inertial measurement unit (IMU) sensors for measurement of multi-joint range of motion, posture, gait, and muscle function
ICD-10 Diagnosis	
	All diagnoses

References

Peer Reviewed Publications:

1. Bento T, Cortinhas A, Leitão JC, Mota MP. Use of accelerometry to measure physical activity in adults and the elderly. Rev Saude Publica. 2012; 46(3):561-570.
2. Boroojerdi B, Ghaffari R, Mahadevan N, et al. Clinical feasibility of a wearable, conformable sensor patch to monitor motor symptoms in Parkinson's disease. Parkinsonism Relat Disord. 2019; 61:70-76.
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measures in a phase 1 Parkinson's disease clinical trial. Mov Disord. 2018; 33(8):1287-1297.
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16. Mehrang S, Jauhiainen M, Pietil J, et al. Identification of Parkinson's disease utilizing a single self-recorded 20-step walking test acquired by smartphone's inertial measurement unit. Conf Proc IEEE Eng Med Biol Soc. 2018; 2018:2913-2916.
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Government Agency, Medical Society, and other Authoritative Publications:

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Websites for Additional Information

1. National Institute of Neurological Disorders and Stroke. Tremor. Available athttps://www.ninds.nih.gov/health-information/disorders/essential-tremor. Accessed on February 8, 2024.

Index

The use of specific product names is illustrative only. It is not intended to be a recommendation of one product over another, and is not intended to represent a complete listing of all products available.

Document History

Status	Date	Action
Reviewed	02/15/2024	Medical Policy & Technology Assessment Committee (MPTAC) review. Revised Rationale, Background, References, and Websites sections.
	12/28/2023	Updated Coding section with 01/01/2024 CPT changes; removed 0533T, 0534T, 0535T, 0536T deleted as of 01/01/2024, replaced by 95999 NOC.
Reviewed	02/16/2023	MPTAC review. Updated Description, Background, Definitions, References and Websites sections. Updated Coding section to add 0778T.
Reviewed	02/17/2022	MPTAC review. Updated Rationale, References, and Websites sections.
Reviewed	02/11/2021	MPTAC review. Updated Rationale, References, and Websites sections.
Reviewed	02/20/2020	MPTAC review. Updated Rationale, References, and Websites sections.
Revised	03/21/2019	MPTAC review. Removed “FDA approved” from Position Statement. Updated Rationale, Background, References, and Websites sections. Updated Coding section to add 0533T-0536T.
Reviewed	03/22/2018	MPTAC review. The document header wording updated from “Current Effective Date” to “Publish Date.” Updated Rationale, Background, Definitions, References, and Websites sections.
Reviewed	05/04/2017	MPTAC review. References were updated.
Reviewed	05/05/2016	MPTAC review. The Background section and References were updated. Removed ICD-9 codes from Coding section.
Reviewed	05/07/2015	MPTAC review. References were updated.
	01/01/2015	Updated Coding section with 01/01/2015 CPT changes; removed 0199T deleted 12/31/2014.
Reviewed	05/15/2014	MPTAC review. The Background section and References were updated.
Reviewed	05/09/2013	MPTAC review. The Rationale, Definitions and References were updated.

Reviewed	05/10/2012	MPTAC review. The Rationale and References were updated.
Reviewed	05/19/2011	MPTAC review. References were updated.
Reviewed	05/13/2010	MPTAC review. The Rationale and References were updated.
	01/01/2010	Updated Coding section with 01/01/2010 CPT changes.
New	05/21/2009	MPTAC review. Initial document development.

Applicable to Commercial HMO members in California: When a medical policy states a procedure or treatment is investigational, PMGs should not approve or deny the request. Instead, please fax the request to Anthem Blue Cross Grievance and Appeals at fax # 818-234-2767 or 818-234-3824. For questions, call G&A at 1-800-365-0609 and ask to speak with the Investigational Review Nurse.

Federal and State law, as well as contract language, including definitions and specific contract provisions/exclusions, take precedence over Medical Policy and must be considered first in determining eligibility for coverage. The member's contract benefits in effect on the date that services are rendered must be used. Medical Policy, which addresses medical efficacy, should be considered before utilizing medical opinion in adjudication. Medical technology is constantly evolving, and we reserve the right to review and update Medical Policy periodically.