
Medical Policy



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***Current Policy Effective Date: 7/1/20**
(See policy history boxes for previous effective dates)

Title: Physiologic Recording of Tremor Using Accelerometer(s) and Gyroscope(s)

Description/Background

The differential diagnosis of tremor is mainly based on clinical criteria. However, these criteria are in some cases not sufficient to differentiate between different tremor forms. Neurophysiological investigations have led to a better understanding of tremor and have also shown some significance for the differential diagnosis. Commonly used physiological investigation methods are long-term accelerometry, electromyography, analysis of single motor units firing or measuring of long-latency and stretch reflexes. The main parameters obtained by these methods are tremor amplitude and frequency, but the use of more subtle evaluation methods such as waveform analysis of tremor curves or activation patterns of antagonistic muscles can give additional information.

The most common pathological tremors are essential tremor (ET) and tremor in Parkinson's disease (PD). ET is usually present during posture and action, whereas the most common tremor form in Parkinson's disease is resting tremor. Tremor in PD is usually accompanied by other clinical symptoms such as bradykinesia and rigidity. When all the typical features are present, these two tremor forms are easy to distinguish on a clinical basis. However, in the early phase of the diseases, when the signs and symptoms are most subtle, diagnosis may be difficult. It has been estimated that 20% of cases of each condition are misdiagnosed. Thus, several quantitative electrophysiological criteria were investigated with respect to their ability to separate PD from ET.

Long-term EMG has been proposed as a method for the quantification of pathological tremors. Studies have been undertaken to develop a long-term EMG-based automated analysis procedures to separate parkinsonian tremor from essential tremor. The advantage of using long-term recordings is obvious, since tremor characteristics can change considerably over the period of a day. Previous studies have shown that the long-term EMG method may be valid and reliable for measuring and quantification of pathological tremor. Its usefulness in

monitoring therapy effects has also been demonstrated. Due to the obvious advantage of monitoring during normal daily-life activities, several types of ambulatory long-term monitoring based on accelerometers, gyroscopes and actigraphs have been proposed as a method to detect and quantify tremor and other motor symptoms in PD. It has been proposed that this testing may enable the distinction between pathological and physiological tremor and helps in differentiation of various types of pathological tremor.

This policy describes a type of tremor analysis device that includes an accelerometer and a gyroscope. These types of devices attach to the individual's arm (or finger). Once attached, the person is then asked to do several tasks, such as resting with his hands in his lap for several seconds, holding his arms straight out in front of him for several seconds, and extending his arm and touching his nose. Some models of these devices also include an electromyography (EMG) testing component. These devices are proposed for use in diagnosing tremor and in deep brain stimulation to guide adjustments to the neurostimulator settings.

There are several motion analysis accelerometers on the market for various applications including evaluation of physical exercise, weight reduction progress, and motion disorders, (e.g., essential tremor) associated with certain conditions, such as Parkinson's disease. One such device is the Kinesia™ (Cleveland Medical Devices, Inc., 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 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).

The Kinesia device consists of a wrist module and ring sensor. Motion sensors including accelerometers and gyroscopes are integrated into a finger-worn unit to capture three dimensional motions. The finger-worn sensor unit is worn on a finger band and is connected to a wrist-worn module by a thin flexible wire. The wrist module provides input for two channels of electromyography, battery power, on board memory, and an embedded radio for real-time wireless transmission of the collected signals. The wrist module is worn on a comfortable, adjustable wristband. The signals are communicated between the wrist module and the computer unit using wireless technology based on 2.4-2.484 gigahertz (GHz) frequencies. The wrist module includes a push button diary, so that the individual can indicate when he has taken his medication and when his symptoms are severe.

Another device, called the Tremormeter® (FlexAble Systems, Inc., Fountain Hills, AZ) received 510(k) FDA clearance on July 25, 2001. The manufacturer describes it as a battery powered, hand-held, self-contained programmable device that includes a three-axis accelerometer that attaches to an individual's finger and transmits triaxial tremor measurements to a personal computer (PC) for further analysis, display, printing or storage. The Tremormeter is intended to

- Measure and record triaxial tremor movements to optionally combine the three axis tremor information into a single measurement of total tremor movement by a proprietary algorithm that eliminates some of the rotational orientation and other artifacts
- To display the information graphically
- To transfer the data to a personal computer for further analysis, display, printing or storage.

To date, there is a lack of adequate studies on the clinical utility of accelerometers. Published, peer-reviewed medical evidence is insufficient to support the safety and efficacy of these devices, as compared to conventional testing modalities.

Regulatory Status:

- U.S. Food and Drug Administration (FDA). Center for Devices and Radiologic Health (CDRH). Kinesia™ (Cleveland Medical Devices, Inc., Cleveland, OH). K063872. April 6, 2007. Available at: http://www.accessdata.fda.gov/cdrh_docs/pdf6/K063872.pdf. Accessed on October 8, 2014.
 - U.S. Food and Drug Administration (FDA). Center for Devices and Radiologic Health (CDRH). Tremometer® (FlexAble Systems, Inc. Fountain Hills, AZ). K010270. July 25, 2001. Available at: http://www.accessdata.fda.gov/cdrh_docs/pdf/K010270.pdf. Accessed on October 8, 2014.
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Medical Policy Statement

Physiologic recording of tremor using accelerometer(s) and gyroscope(s) is experimental/investigational. While this testing may be safe, its effectiveness in differentiating between specific types of tremor has not been proven to change patient management or improve patient outcomes.

Inclusionary and Exclusionary Guidelines (Clinically based guidelines that may support individual consideration and pre-authorization decisions)

N/A

CPT/HCPCS Level II Codes *(Note: The inclusion of a code in this list is not a guarantee of coverage. Please refer to the medical policy statement to determine the status of a given procedure)*

Established codes:

N/A

Other codes (investigational, not medically necessary, etc.):

95999

Rationale

Testing the clinical validity of accelerometers requires peer-reviewed, controlled studies comparing the information provided by an accelerometer to a qualitative clinical patient assessment. Such studies should identify the utility of using the obtained information to improve the clinical management and outcomes of patients with tremor.

A German study by Raethjen et al, conducted in two centers in 2004, compared the quantitative tremor analyses of two independent normal cohorts using very similar methods. This study compared diagnostic findings with lab-specific normal values. A significant reduction of tremor frequency under 1000 g weight load (greater than 1 Hz), and a lack of rhythmic EMG activity at the tremor frequency in/around 85-90% of the recordings were noted findings in both centers.³⁰

The authors determined that differences in frequency and total power indicated that clinical findings depend on the recording conditions and that normative data needs to be established, in order to standardize tremor analysis using accelerometer devices. It is noted that this study focused on the technical capability of the accelerometer device and not its clinical utility in the evaluation of tremor.

Another small study was conducted in the U.S. by Eible et al in 2006; the study purpose was to determine the change in tremor amplitude that corresponds to a 1-point change in a typical 5-point TRS, (which is the Tremor Rating Scale that is commonly used in the clinical assessment of tremor). This study addressed the clinical validity of the accelerometer itself. While the authors concluded that knowledge of the relationship between TRS and precise measures of tremor is useful in interpreting the clinical significance of changes in TRS produced by disease or therapy, this study did not address how this information could be used to improve treatment management.⁶

A study was done in 2007 by Machowska-Majchrzak for the purpose of developing a long-term EMG-based automated analysis procedure that separates Parkinsonian tremor from essential tremor. Using long-term EMG, tremor was recorded in 45 consecutive patients, 26 with Parkinson's disease (PD) and 19 with essential tremor (ET). Eight tremor parameters were generated automatically. By stepwise backward regression a subset of these criteria was extracted to achieve an automated classification of the tremor by a mathematical model. The obtained model was then tested on a new group of 13 patients in early stages of the disease. However, this was only one study and provided no outcomes data.²¹

In 2011, there were a couple of small studies which investigated the use of accelerometric measurements for the evaluation of tremor in specific dyskinetic conditions, including Parkinson disease and stroke. Inconsistent conclusions have been reached from these studies. The authors admitted that there is a need for further study to determine the clinical utility of these testing devices as well as patient selection criteria for their use.^{5,15}

Additional studies done in 2012 investigated the clinical validity of accelerometric measurements to evaluate physical activity and gait variables in the elderly and in those with hip osteoarthritis. Different devices, methods of data analysis and reporting were used. The authors acknowledged the need for further research to standardize testing methods and data reporting that compare devices in clinical. Given the lack of studies on the clinical utility of accelerometers, the published evidence is insufficient to support the safety and efficacy of these devices, or to determine the effect of this testing on patient outcomes.^{2,14}

Most recently, McGregor et al (2018) studied the Parkinson's KinetiGraph (PKG) system to assess night time sleep in subjects with Parkinson's disease. The study consisted of 155 people aged over 60 and without Parkinson's disease (controls), 72 people with Parkinson's disease and 46 subjects undergoing a polysomnogram. The PKG system uses a wrist worn logger to capture acceleration and derive a bradykinesia score (BKS) every 2 min over 6 days.

The BKS ranges from 0-160 with higher scores associated with lesser mobility. Previously it was shown that BKS > 80 were associated with day time sleep and used this to produce scores for night time sleep: Efficiency (Percent time with BKS > 80), Fragmentation (Average duration of runs of BKS > 80) and Sleep Quality (BKS > 111 as a representation of atonia). There was a fair association with BKS score and sleep level as judged by PSG. Using these PKG scores, it was possible to distinguish between normal and abnormal PSG studies with good selectivity (86%) and sensitivity (80%). The PKG's sleep scores were significantly different in PD and Controls and correlated with a subject's self-assessment (PDSS 2) of the quality, wakefulness and restlessness. Using both the PDSS 2 and the PKG, it appeared that sleep disturbances were evident early in disease in many PD subjects and that subjects with poor night time sleep were more likely to have day time sleepiness. This system shows promise as a quantitative score for assessing sleep in Parkinson's disease.²⁷

While this testing may be safe, its clinical utility remains unclear.

Government Regulations

National:

There is no national coverage determination on this topic. Code has no fee assigned to it.

Local:

There is no local coverage determination on this topic. Code has no fee assigned to it.

(The above Medicare information is current as of the review date for this policy. However, the coverage issues and policies maintained by the Centers for Medicare & Medicare Services [CMS, formerly HCFA] are updated and/or revised periodically. Therefore, the most current CMS information may not be contained in this document. For the most current information, the reader should contact an official Medicare source.)

Related Policies

- Automated Nerve Conduction Studies
 - Deep Brain Stimulation for the Treatment of Tremors
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References

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The articles reviewed in this research include those obtained in an Internet based literature search for relevant medical references through February 2020, the date the research was completed.

Joint BCBSM/BCN Medical Policy History

Policy Effective Date	BCBSM Signature Date	BCN Signature Date	Comments
9/1/09	7/16/09	6/16/09	Joint policy established
9/1/12	6/12/12	6/19/12	Updated references; no change in policy status.
1/1/14	10/17/13	10/25/13	Rationale and references updated. No change in policy status.
3/1/15	12/12/14	12/29/14	No change in policy status.
7/1/16	4/19/16	4/19/16	Routine maintenance, no change in policy statement. 0199T deleted, NOC 95999 added.
7/1/17	4/18/17	4/18/17	Routine maintenance, references added, policy status unchanged.
7/1/18	4/17/18	4/17/18	Updated rationale section, added reference # 27. No change in policy status.
7/1/19	4/16/19		Routine policy maintenance. No change in policy status.
7/1/20	4/14/20		Routine policy maintenance. No change in policy status. No new literature, no clinical trials found. Policy retired.

Next Review Date: This procedure has been determined to be obsolete and is no longer subject to routine review.

BLUE CARE NETWORK BENEFIT COVERAGE
POLICY: PHYSIOLOGIC RECORDING OF TREMOR USING ACCELEROMETER(S) AND
GYROSCOPE(S)

I. Coverage Determination:

Commercial HMO (includes Self-Funded groups unless otherwise specified)	Not covered.
BCNA (Medicare Advantage)	See government section.
BCN65 (Medicare Complementary)	Coinsurance covered if primary Medicare covers the service.

II. Administrative Guidelines:

N/A