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Clinical Policy Bulletin:
Actigraphy and Accelerometry

Revised February 2015

Number: 0710

Policy

Aetna considers actigraphy testing/measurement (e.g., the Actiwatch, AW-64, and Emfit; not an all-inclusive list) experimental and investigational for the following indications (not an all-inclusive list) because there is insufficient scientific evidence in the medical literature to support its use in clinical practice.

Detection of seizures during sleep
Diagnosis of sleep disorders (e.g., periodic limb movements of sleep and sleep-wake disturbance)
Evaluation of depression
Evaluation of motor fluctuations in persons with Parkinson’s disease
Evaluation of post-traumatic stress disorder
In the setting of opioid detoxification

Aetna considers accelerometry (e.g., the Kinesia, and the Tremerometer) experimental and investigational for the following indications (not an all-inclusive list) because there is insufficient scientific evidence in the medical literature to support its use in clinical practice.

Evaluating functional ability in the elderly
Gait analysis in persons with hip osteoarthritis
Measuring disease activity in children with eczema
Monitoring of physical activity after stroke
Monitoring of physical motion and muscle activity to quantify kinematics of movement disorder symptoms (e.g., tremor)

Aetna considers a epilepsy monitoring system utilizing accelerometry and heart rate monitoring experimental and investigational for diagnosing nocturnal epilepsy and for all other indications.

See also CPB 0004 - Obstructive Sleep Apnea in Adults, and CPB 0330 - Multiple Sleep Latency Test (MSLT).
Background

Actigraphy Testing:

Actigraphy testing consists of a small portable device (actigraph) that senses physical motion and stores the resulting information. Actigraphy testing has been predominantly used in research studies to evaluate rest-activity cycles in patients with sleep disorders, to determine circadian rhythm activity cycles, and to determine the effect of a treatment on sleep. The actigraph is most commonly worn on the wrist, but can also be worn on the ankle or trunk of the body. Actigraphy testing is based on the assumption that movement is reduced during sleep compared with wakefulness and that activity level can be used as a diagnostic indicator for sleep disorders.

The Actiwatch™ (Mini-Mitter Co., Inc., Bend, OR) is a battery-operated device that has received 510(k) premarket notification from the U.S. Food and Drug Administration (FDA) to be used to automatically collect and score data for sleep parameters, analyze circadian rhythms, and assess activity in any instance where quantifiable analysis of physical motion is desired. Thus, the manufacturer was not required to submit to the FDA the evidence of efficacy that is necessary to support a premarket approval application.

According to the manufacturer’s website, the Actiwatch utilizes a motion sensor known as an “accelerometer” to monitor the occurrence and degree of motion and produces a small signal. The magnitude and duration of the signal depends on the amount of motion. The activity signals are amplified and digitized and stored as activity counts. Recordings can be conducted for days or weeks on patients in their own homes. When the recording period is complete, the stored movement data can be transferred to a computer for analysis. Data may be expressed graphically as actograms or reported numerically as total activity counts per epoch, thereby estimating sleep latency, total sleep time, number and frequency of awakenings, and “sleep efficiency.” The Actiwatch has been proposed as a diagnostic parameter for a number of sleep disorders including insomnia, restless legs syndrome/periodic limb movement disorder, circadian-rhythm disorders, and sleep apnea.

Methods of assessing sleep complaints have included history from the patient and bed partner, use of sleep history questionnaires, sleep-wake diaries, actigraphy and polysomnography (PSG). However, a review of the literature produced few validation studies that incorporated large sample sizes, typical sleep clinic patients, or comparisons with subjective reports of sleep parameters. There is little agreement among authors concerning methods for effective assessment and subsequent differential diagnosis of sleep disorders (Kushida et al, 2001; Bjorvatn et al, 2001). Furthermore, some of the research studies failed to find relationships between sleep measures and health-related symptoms.

Practice guidelines for actigraphy established by the Standards of Practice Committee of the American Academy of Sleep Medicine (AASM) (Littner et al, 2003) stated that actigraphy testing is reliable and valid for detecting sleep in normal, healthy populations. However, the guidelines stated that actigraphy
testing is not indicated for the routine diagnosis, assessment, or management of any of the sleep disorders. A 2007 update of the AASM guidelines (Morgenthaler et al, 2007) only recommended actigraphy as a "standard" to estimate total sleep time in persons with obstructive sleep apnea syndrome (OSA) "when PSG is unavailable" and, consistent with the 2003 guideline, as "a way to assist in determining sleep patterns in normal, healthy adult populations." The recommendations of the AASM are categorized as standards, guidelines, or options. Standards describe a "generally accepted patient-care strategy, which reflects a high degree of clinical certainty." The term standard generally implies the use of Level 1 evidence (defined as blind, prospective comparison of results obtained by actigraphy to those obtained by a reference standard on an appropriate spectrum of subjects and number of patients, which directly addresses the clinical issue), or overwhelming Level 2 evidence (defined as comparison of results obtained by actigraphy to those obtained by a reference standard but blinding not specified, not prospective, or on a limited spectrum of subjects or number of patients). Guidelines reflect "a moderate degree of clinical certainty", and implies the use of Level 2 evidence or a consensus of Level 3 evidence (defined as a comparison of results obtained by actigraphy to the mean value of a reference standard, but not direct within-subject comparison, or otherwise methodologically limited). Options reflect "uncertain clinical use" and imply either inconclusive or conflicting evidence or conflicting expert opinion. According to these guidelines, actigraphy is a standard "generally accepted patient care strategy .... reflecting a high degree of clinical certainty" for estimating total sleep time in OSA when PSG is unavailable. Given limitations of the evidence, all the other clinical indications for actigraphy that were considered were classified as guidelines ("moderate degree of clinical certainty") or options ("uncertain clinical use"). The guideline summarized limitations of the existing data on actigraphy, noting that "few studies" actually specified whether investigators were blinded to the results of other studies, and most of these lacked a description of blinding. The guideline also found that few of the studies reviewed had provided technical details related to the administration and scoring of actigraphy. The AASM Standards of Practice Committee indicated the need for additional research in the following areas:

- Comparison of results from different actigraphy devices and the variety of algorithms used to evaluate actigraphy data in order to further establish standards of actigraphy technology.
- Additional study addressing the reliability and validity of actigraphy compared to reference standards, such as polysomnography, and the circadian rhythms of basic physiologic functions, such as temperature, cortisol, and melatonin levels.
- Research is needed to establish standards for setting start and stop times of the sleep and wake periods when using actigraphy, including techniques such as event markers or sleep diaries, and other methods in the study of populations where these techniques may not be valid.
- More research is needed to assess the reliability of actigraphy under various clinical circumstances, and to determine what parameters may be used to assess the quality of actigraphic data.
- There is a need for well-designed studies that include technical details related to the administration and scoring of actigraphy. The guideline
stated that "in much of the existing literature, there is an inadequate
description of whether visual inspection of data is performed, how missing
data is handled, and other important decisions made in the analysis of
actigraphy data."

Further work is needed to clarify the relative and unique contributions of
actigraphy, polysomnography and sleep logs in the diagnosis of sleep
disorders and measurement of treatment effects.
The guidelines stated that the use of actigraphy in hypersomnia
populations, especially as an adjunct to the Multiple Sleep Latency Test,
should be tested to establish an evidence-based recommendation for the
use of actigraphy in the clinical evaluation and management of
hypersomnia.

According to a review by Sadeh and Acebo (2002), actigraphy is less useful for
documenting sleep-wake in persons who have long motionless periods of
wakefulness (e.g. insomnia patients) or who have disorders that involve altered
motility patterns (e.g., sleep apnea). The authors stated the pitfalls of actigraphy
testing are: (i) validity has not been established for all scoring algorithms or
devices, or for all clinical groups; (ii) actigraphy is not sufficient for diagnosis of
sleep disorders in individuals with motor disorders or high motility during sleep;
and (iii) the use of computer scoring algorithms without controlling for potential
artifacts can lead to inaccurate and misleading results.

It is difficult to establish actigraphy testing standards at the present time, given the
variety of different actigraphs available, the different technology and algorithms for
detecting movement, and the lack of standardized units of activity measures.
Thus, it is not clear how actigraphic information would be used in the treatment and
management of patients with sleep disorders (Edinger et al, 2004). Patients who
lie still but are awake for prolonged periods of time will have their sleep time
overestimated. Similarly, patients with excessive movements during sleep may be
considered to be awake and have an underestimation of sleep time. Additional
research comparing actigraphic methodology is needed to establish standards of
actigraphy testing.

The Watch_PAT 100 is a portable device that measures peripheral arterial
tonometry, pulse oximetry, and actigraphy. Although there are published studies
suggesting that the Watch_PAT may be useful in diagnosing OSA (Pillar et al,
2003; Ayas et al, 2003; and Bar et al, 2003), there is currently insufficient scientific
evidence in the medical literature to support its use for the diagnosis of obstructive
sleep apnea (OSA).

Ayas et al (2003) assessed the accuracy of the Watch_PAT100 to diagnose OSA.
A total of 30 adult subjects with and without suspected OSA simultaneously had a
standard in-laboratory PSG and wore the Watch_PAT100 during a full-night
recording. PSG sleep and respiratory events were scored according to standard
criteria. Watch_PAT data were analyzed with an automated computerized
algorithm which calculated the frequency of respiratory events per hour of
actigraphy measured sleep using a combination of peripheral arterial tonometry
(PAT) signal attenuation, desaturation on pulse oximetry, and changes in heart
rate. This yielded a PAT apnea hypopnea index (AHI). Mean age was 47.0 +/-
14.8 years, mean body mass index 31.0 +/- 7.6 kg/m2, mean PSG AHI 23 +/- 23.9
events per hour, and mean PAT AHI 23 +/- 15.9 events per hour. There was a significant correlation between PAT AHI and AHI by PSG ($r = 0.87$, $p < 0.001$). To assess sensitivity and specificity of the Watch_PAT, the authors constructed receiver operator characteristic (ROC) curves using a variety of AHI threshold values (10, 15, 20, and 30 events per hour). Optimal combinations of sensitivity and specificity for the various thresholds were 82.6/71.4, 93.3/73.3, 90.9/84.2, and 83.3/91.7, respectively. The authors concluded that the Watch_PAT is a device that can detect OSA with reasonable accuracy. Thus, the Watch_PAT may be a useful method to diagnose OSA. They noted that "[p]rior to widespread use of the device, further studies are needed. These include verification of accuracy and ease of use in an ambulatory setting, studies in other medical centers, and studies including more patients with non-respiratory causes of sleep fragmentation. Nevertheless, the Watch_PAT may become a useful technology to diagnose and manage patients with OSA."

Moreover, a technology assessment on portable monitoring devices for diagnosing OSA prepared for the Agency for Healthcare Research and Quality (AHRQ, 2004) evaluated the evidence on the clinical value of Watch_PAT. It found that the quality of evidence to be fair for the study by Bar et al (2003), while the quality of evidence is poor for the studies by Pillar et al (2003) and Ayas et al (2003). It concluded that the new body of evidence does not materially change earlier findings regarding in-home devices for diagnosing OSA -- there is inadequate to support the use of unattended portable multi-channel sleep testing for the diagnosis of OSA. Furthermore, Acebo and LeBourgeois (2006) stated that although actigraphy maybe suitable for documenting and evaluating some sleep disorders, its role in clinical diagnosis is limited.

In a prospective randomized study with blinded analysis, Garcia-Diaz et al (2007) ascertained the utility and reliability of a respiratory polygraphy (RP) device with actigraphy in the diagnosis of sleep apnea-hypopnea syndrome (SAHS). A total of 62 patients with suspected SAHS were enrolled in the following 2 RP studies: (i) one in the sleep laboratory (sleep laboratory RP [LRP]), simultaneously with polysomnography; and (ii) the other at home (home RP [HRP]). To study the inter-observer reliability of RP, 2 manual analyses were carried out by 2 different researchers. In LRP, when the respiratory disturbance index was calculated using the total sleep time estimated by actigraphy (RDI) as a denominator, the sensitivity ranged between 94.6 % and 100 %, and the specificity between 88 % and 96.7 % for the different cut-off points of the apnea-hypopnea indexes studied. When the respiratory disturbance index was calculated according to the total recording time (RDI TRT), the sensitivity was slightly lower (91.6 % to 96.9 %) and the specificity was similar (92 % to 96.7 %). In HRP, the sensitivity of the RDI ranged between 83.8 % and 95.8 %, and the specificity between 92 % and 100 %, whereas, when the RDI TRT was used, the sensitivity was between 83.8 % and 87.5 %, and the specificity was between 94.7 % and 100 %. With regard to inter-observer reliability, the intra-class correlation coefficient for the RDI of the two analyses of the RP was 0.99 for both LPR and HPR. The authors concluded that HPR is an effective and reliable technique for the diagnosis of SAHS, although it is less sensitive than LRP. Furthermore, wrist actigraphy improves the results of HRP only slightly.
Paquet and associates (2007) assessed the ability of actigraphy compared to PSG to detect wakefulness in subjects submitted to 3 sleep conditions with different amounts of wakefulness: a nocturnal sleep episode and 2 day-time recovery sleep episodes, one with placebo and one with caffeine (200 mg). A second objective was to compare the ability of 4 different scoring algorithms (2 threshold algorithms and 2 regression analysis algorithms) to detect wake in the 3 sleep conditions. A total of 15 healthy subjects aged between 20 and 60 years (7 males and 8 females) were included in this study. An epoch-by-epoch comparison between actigraphy and PSG showed a significant decrease in actigraphy accuracy with increased wakefulness in sleep conditions due to the low sleep specificity of actigraphy (generally less than 50 %). Actigraphy over-estimated total sleep time and sleep efficiency more strongly in conditions involving more wakefulness. Compared to the 2 regression algorithms, the 2 threshold algorithms were less able to detect wake when the sleep episode involved more wakefulness, and they tended to alternate more between wake and sleep in the scoring of long periods of wakefulness resulting in an over-estimation of the number of awakenings. The authors concluded that the very low ability of actigraphy to detect wakefulness casts doubt on its validity to measure sleep quality in clinical populations with fragmented sleep or in situations where the sleep-wake cycle is challenged, such as jet-lag and shift-work.

Silnick and colleagues (2008) compared actigraphy with videosomnography in preschool-aged children, with special emphasis on the accuracy of detection of night-time awakenings. A total of 58 subjects wore an actigraph for 1 week and were videotaped for 2 nights while wearing the actigraph. Participants were solitary sleepers, studied in their homes. One group (n = 22) was diagnosed with autism, another group (n = 11) had developmental delays without autism, and a third group (n = 25) were typically developing children; age ranged from 28 to 73 months (mean age of 47 months); 29 boys and 29 girls. Nocturnal sleep and wakefulness were scored from simultaneously recorded videosomnography and actigraphy. The accuracy of actigraphy was examined in an epoch-by-epoch comparison with videosomnography. Findings were 94 % overall agreement, 97 % sensitivity, and 24 % specificity. Statistical corrections for overall agreement and specificity resulted in an 89 % weighted-agreement and 27 % adjusted specificity. The authors concluded that actigraphy has poor agreement for detecting nocturnal awakenings, compared with video observations, in preschool-aged children.

Gschliesser et al (2009) compared periodic leg movement (PLM) counts obtained with PSG to those obtained from 2 actographical devices (Actiwatch and PAM-RL). A total of 24 patients underwent full-night actigraphy with Actiwatch from both legs and simultaneous PSG. Out of these patients, 10 had additional actigraphy with PAM-RL. Bilateral and unilateral PLM indices (PLMI) for both actographical devices were calculated for time in bed and compared to polysomnographic PLMI. Additionally, a comparison between the 2 different actographical devices was performed. Overall, PLMI obtained with Actiwatch were significantly lower than those obtained with PSG (21.2 +/- 25.6/hr versus 34.4 +/- 30.7/hr; p < 0.001), whereas the PLMI from PAM-RL were significantly higher than in PSG (63.6 +/- 39.3/hr versus 37.0 +/- 33.5/hr; p = 0.009). In direct comparison, Actiwatch gave significantly lower PLMI than the PAM-RL (p = 0.005). The correlations between
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Actiwatch and PSG (rho = 0.835, p < 0.001), PAM-RL and PSG (rho = 0.939, p < 0.001), and Actiwatch and PAM-RL (rho = 0.915, p < 0.001) were significant. Unilateral actigraphy compared to standard PSG gave less consistent findings. When comparing different settings of the PAM-RL, manual threshold setting resulted in PLMI that were no longer different from PSG (p = 0.074), in contrast to the default threshold setting. The authors concluded that the Actiwatch under-estimated and the PAM-RL over-estimated PLMI compared to PSG. Whereas PLMI obtained with the 2 actigraphical devices and PSG were highly correlated, they differed in mean values. Thus, PSG, actigraphy and also the different actigraphical devices can not be interchanged in longitudinal studies, and actigraphy should not be used for diagnostic decision-making based on PLM indices. The best approximation to PSG PLMI was achieved by using manual threshold setting with the PAM-RL.

In a review on ambulatory monitoring of sleep disorders, Tahmasian et al (2010) noted that actigraphy can not stand alone as a diagnostic tool for all clinical groups; especially so with those diagnosed with sleep disorders with significant motility or long catatonic periods of wakefulness during sleep.

Perez Lloret et al (2010) compared activity level in the "off-state", "on-state", and dyskinetic periods as evaluated either by a physician during a levodopa challenge or by a 72-hr on-off diary self-evaluation in the ambulatory setting. Finally, the effect of daily activities on motor activity in Parkinson's disease (PD) and healthy controls was further explored. The study was conducted in 3 consecutive phases: (i) for phase I, in which the on-state, off-state, and dyskinesia were evaluated using actigraphy, recordings were made during standard acute levodopa challenge in 9 dyskinetic PD patients; (ii) for phase II, a different set of 16 dyskinetic PD patients was monitored in the ambulatory setting for 72 consecutive hrs by actigraphy and a standardized on-off diary; and (iii) for phase III, 62 PD patients and 14 age- and sex-matched healthy controls wore an actigraph and completed a daily activities diary for 7 days. No differences in activity level between on-state and off-state during the acute levodopa challenge (phase I) or the 72-hr ambulatory period (phase II) were found. Activity during dyskinesia periods was significantly higher than during on-state periods without dyskinesia (p < 0.01). During the phase III study, dyskinetic PD patients and healthy controls showed higher actigraphy-measured activity as compared to de novo, stable, or fluctuating PD (p < 0.0001), which remained unchanged by daily activities performed during the study period. Tremor UPDRS scores did not correlate with activity level. The authors concluded that these results confirm the lack of specificity of simple wrist-worn actigraphy and further suggested it may be suitable for dyskinesia assessment but not for on-state and off-state evaluation.

Pjrek and colleagues (2012) evaluated the differential effects of opioid detoxification with methadone or buprenorphine on activity, circadian rhythm, and sleep. A total of 42 consecutive inpatients with opiate addiction were switched to either methadone or buprenorphine and gradually tapered down over the course of 2 to 3 weeks. There were no significant differences in co-medication (lofexidine, quetiapine, and valproic acid) between the methadone and buprenorphine groups. Patients in the methadone group showed 11 % lower activity and were 24 minutes phase delayed as compared with buprenorphine-treated patients, whereas the latter had 2.5 % lower sleep efficiency and 9 % shorter actual sleep time. These
significant group differences were most pronounced for the lowest doses (less than or equal to 20% of maximum individual daily dose, i.e., at the end of withdrawal representing late withdrawal effects). Furthermore, for the total sample, these investigators found a significant decrease in the relative amplitude of the sleep-wake cycle and worsening of all actigraphic sleep parameters from the higher (100% to 20%) to the lowest doses (20% to 0%). The acrophase of the circadian rhythm displayed a phase advance (-88 minutes) from the highest (100% to 80%) to the lower doses (80% to 0%) in methadone-treated patients. The authors concluded that opioid tapering with methadone or buprenorphine leads to characteristic changes of the rest-activity cycle, but further study is needed to validate these findings.

Plante (2014) stated that periodic limb movements of sleep (PLMS) are repetitive, stereotyped movements that can disrupt sleep and result in insomnia, non-restorative sleep, and/or daytime sleepiness. Currently, PSG is the gold standard and only clinically acceptable means of quantifying PLMS. Leg-worn actigraphy is an alternative method of measuring PLMS, which may circumvent many of the economic and technical limitations of PSG to quantify nocturnal leg movements. However, the use of leg actigraphy as a diagnostic means of assessing PLMS has not been systematically evaluated. In this review, the use of leg-worn actigraphy to measure PLMS was systematically evaluated, using both qualitative and quantitative assessment. Findings demonstrate significant heterogeneity among a limited number of studies in terms of type of actigraph utilized, position of the device on the lower extremity, and methods employed to count PLMS. In general, common accelerometers vary in their sensitivity and specificity to detect PLMS, which is likely related to the technical specifications of a given device. A current limitation in the ability to combine data from actigraphs placed on both legs is also a significant barrier to their use in clinical settings. The author concluded that further research is needed to determine the optimal methods to quantify PLMS using leg actigraphy, as well as specific clinical situations in which these devices may prove most useful.

Burton et al (2013) noted that altered physical activity is an important feature of depression. It is manifested in psychomotor retardation, agitation and withdrawal from engagement in normal activities. Modern devices for activity monitoring (actigraphs) make it possible to monitor physical activity unobtrusively but the validity of actigraphy as an indicator of mood state is uncertain. These researchers performed a systematic review of digital actigraphy in patients with depression to investigate the associations between measured physical activity and depression. Studies were identified from Medline, EMBASE and Psycinfo databases and included if they were either case control or longitudinal studies of actigraphy in adults aged between 18 and 65 diagnosed with a depressive disorder. Outcomes were day-time and night-time activity and actigraphic measures of sleep. These investigators identified 19 eligible papers from 16 studies (412 patients). Case control studies showed less day-time activity in patients with depression (standardized mean difference -0.76, 95% CI: -1.05 to -0.47). Longitudinal studies showed moderate increase in day-time activity (0.53, 0.20 to 0.87) and a reduction in night-time activity (-0.36, -0.65 to -0.06) over the course of treatment. The authors concluded that actigraphy is a potentially valuable source of additional information about patients with depression. However, there are no clear guidelines for use of actigraphy in studies of patients
with depression. Moreover, they stated that further studies should investigate patients treated in the community; additional work to develop algorithms for differentiating behavior patterns is also needed.

Khawaja et al (2014) noted that patients with post-traumatic stress disorder (PTSD) frequently complain of sleep disturbances such as insomnia and nightmares. Evaluation of sleep disturbances is often difficult due to the subjective nature of the complaints. Polysomnography and other sleep studies are generally not indicated in the evaluation of insomnia or nightmares associated with PTSD. Actigraphy has been used in research to evaluate sleep disturbances in patients with PTSD. These researchers reviewed the literature on the use of actigraphy in evaluation of sleep problems in patients with PTSD. A literature search for articles on the topic was conducted on PubMed using the search algorithm (actigraphy [Title/Abstract] OR actigraphic[Title/Abstract]) AND PTSD[Title/Abstract]. Out of 11 search results, 9 studies in which application of actigraphy had relevance to the primary objective and outcome in PTSD patients with sleep problems were selected for review. These investigators also handpicked 1 additional article from personal communication with their colleagues who had performed some of these studies. The authors concluded that actigraphy has been used to evaluate circadian rhythm sleep disorders. Use of actigraphy in psychiatry clinics is uncommon. There are no data to support that there are specific actigraphic sleep related findings in PTSD patients.

Actigraphy:

Individuals with movement disorders including essential tremor and PD often exhibit tremor, bradykinesia and dyskinesias, which can change rapidly and affect quality of life. Research to develop new treatments for these disorders is ongoing and advent in new therapies requires methodologies that can reliably quantify movement. Available methods include accelerometry, spiography, volumetry, handwriting assessment, handicap/disability scales, as well as handicap/disability questionnaires.

Accelerometry was first suggested in the 1970s, but has only been refined during the past 2 decades. Direct measurement by accelerometry has seen the introduction of the successful implementation of low-power, low-cost electronic sensors that have been employed in clinical and home environments for the constant monitoring of patients (and their controls). The qualitative and quantitative data provided by these sensors enable engineers, clinicians and physicians to work together to help patients with movement disorders in overcoming their physical disability (Godfrey et al, 2008).

In April 2007, Cleveland Medical Devices Inc. (Cleveland, OH) received clearance from the FDA to market Kinesia to be used for monitoring 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. Kinesia, a quantitative motor assessment system, is a compact wireless system that uses accelerometers and gyroscopes to monitor 3-dimensional motion. The device is worn on the wrist and finger of the patient and can be used to monitor upper extremity movement disorder symptoms and their fluctuations. Motion and electromyography information from the patient is wirelessly telemetered to a computer for display and analysis. The Kinesia
software also integrates videos, which guide the patient through tasks known to elicit symptoms, similar to instructions given by a physician when evaluating upper extremity motor symptoms. Tasks completed for evaluating tremor are automatically scored on a 0 to 4 scale, which correlated to the Unified Parkinson's Disease Rating Scale (UPDRS).

Although feasible methods for monitoring movement are available, evidence-based clinical applications of accelerometry in patients with PD have generated mixed results. In particular, there is insufficient evidence that the use of accelerometry is associated with improved health outcomes in PD patients.

Manson and colleagues (2000) noted that new treatments are now becoming available for the management of levodopa-induced dyskinesias (LID) in PD. However, assessment of their effectiveness is limited by the inadequacies of current methods of dyskinesia measurement. The aim of this study was to develop and validate a portable device capable of objectively measuring dyskinesias during normal daily activities. A portable device was developed based on a tri-axial accelerometer, worn on the shoulder, and a data recorder that can record LID. A computer program plots raw acceleration and acceleration over 0.5 Hz frequency bands against time. The acceleration in the different bands can then be compared with the raw acceleration trace, enabling identification and exclusion of confounding activities such as tremor and walking, which have a characteristic appearance on the trace. The validity of this device was assessed on 12 patients and 8 age-matched controls by comparing accelerations in the 1 to 3 Hz frequency band with established clinical dyskinesia rating scales. While wearing the monitor, subjects were video-recorded sitting and during dyskinesia provocation tasks, including mental activation tasks, eating, drinking, writing, putting on a coat, and walking. The dyskinesias were graded with both modified abnormal involuntary movement (AIM) and Goetz scales. The clinical ratings were then compared with the mean acceleration scores. Acceleration in the 1 to 3 Hz frequency band correlated well against both scales, during all individual tasks. Acceleration produced by normal voluntary activity (with the exception of walking, which produced large accelerations, even in controls) was small compared with dyskinetic activity. With walking excluded, the mean acceleration over the rest of the recording time correlated strongly with both the modified AIM (Spearman’s rank \( r = 0.972, p < 0.001 \)) and Goetz \( (r = 0.951, p < 0.001) \) scales. The authors concluded that this method provides an accurate, objective means for dyskinesia assessment, and compares favorably with established methods currently used.

Keijzers et al (2003) developed an objective and automatic procedure to assess the severity of LID in patients with PD during daily life activities. A total of 13 patients were continuously monitored in a home-like situation for a period of approximately 2.5 hrs. During this time period, patients performed approximately 35 functional ADL. Behavior of the patients was measured using tri-axial accelerometers, which were placed at 6 different positions on the body. A neural network was trained to assess the severity of LID using various variables of the accelerometer signals. Neural network scores were compared with the assessment by physicians, who evaluated the continuously video-taped behavior of the patients off-line. The neural network correctly classified dyskinesia or the absence of dyskinesia in 15-min intervals in 93.7, 99.7, and 97.0 % for the arm, trunk, and leg, respectively. In the few cases of mis-classification, the rating by
the neural network was in the class next to that indicated by the physicians using the AIMS score (scale 0 to 4). Analysis of the neural networks revealed several new variables, which are relevant for assessing the severity of LID. The results indicated that the neural network can accurately assess the severity of LID and could distinguish LID from voluntary movements in daily life situations.

On the other hand, findings from other studies did not support the use of accelerometry in evaluating PD patients. Hoff et al (2001) developed parameters for objective ambulatory measurements of LID in patients with PD. A total of 23 PD patients with mild-to-severe LID were submitted to a standardized protocol of 1-minute recordings during rest, talking, stress, and 4 activities of daily life (ADL). Patients were simultaneously monitored with portable multi-channel accelerometry (4 pairs of bi-axial sensors mounted onto the most affected arm, leg, and at the trunk) and recorded by video. The severity of LID was assessed with a modified Abnormal Involuntary Movement Scale (m-AIMS). The signals were analyzed, and every 1/8-second interval the amplitude was obtained of the dominant frequency within 1 to 4 Hz and 4 to 8 Hz frequency bands (Amp 1 to 4 and Amp 4 to 8). For both measures, convergent validity, reproducibility, and responsiveness were determined. In the absence of voluntary movements, a significant relation was found between Amp 1 to 4 and Amp 4 to 8 and m-AIMS. Repeated measurements during rest showed a high reproducibility (intra-class correlation coefficient [ICC] = 0.90 [Amp 1 to 4] and 0.86 [Amp 4 to 8]). The extent to which LID increased with talking and stress correlated significantly (p = 0.02) between the objective and clinical measures (ICC for differences = 0.67). During ADL, LID occurred in a similar frequency band as voluntary movements and only Amp 1 to 4 and Amp 4 to 8 of the trunk and leg sensor remained highly correlated with m-AIMS. The authors noted that although objective measures of LID are reliable and responsive, they failed to distinguish LID from voluntary movements. These measures are of value only when obtained during rest (all sensor sites) or during ADL when derived from those body segments that are normally not involved in these ADL tasks (trunk and leg).

Thielgen et al (2004) extended the use of accelerometry to PD patients in a clinical rehabilitation program, and examined its practicability with respect to the results of the treatment and patients’ compliance. The methodology was tested on 30 patients (17 males, 13 females). The mean age was 64.8 years (s = 8.9). The Hoehn-Yahr index ranged from 1 to 3 (m = 2.3, s = 0.7) and the overall UPDRS between 10 and 74 (m = 42.9, s = 18.1). The data recording included: (i) the registration of tremor under standardized conditions of rest and postural tremor test with and without distraction; (ii) a standard protocol to obtain reference values for body position and movement; and (iii) the 24-hr monitoring. A total of 21 patients could be recorded a second time, on average 18 days after the first recording. Between the 2 registrations, patients received individually tailored drug treatment supplemented with specific activating physiotherapy, ergotherapy measures, and individual psychotherapeutic counseling. Changes between 1st and 2nd recording were evident for the 3 tremor variables, but significant only for the 24-hr ambulatory monitoring. The between and within-subjects correlations of the tremor variables were rather low except the correlations between occurrence and amplitude (between-subjects 0.87; within-subjects 0.67). Conditions of rest and postural tremor test showed a correlation with corresponding segments of the ambulatory monitoring of about 0.50 for the tremor occurrence. The best
prediction of the day-time monitoring was made by the tremor tests with
distraction, whereas the night segment was best predicted by the standard
protocol.

Hoff et al (2004) noted that shortcomings of existing assessment methods in PD
have led to the development of continuous ambulatory multi-channel
accelerometry for the assessment of the core features of PD. Although measures
for hypokinesia, bradykinesia, and tremor have been validated in groups of
patients with PD, it is unclear whether this method is able to detect "on" with or
without dyskinesias, and "off" in individual PD patients. This study addressed the
accuracy of objective ambulatory accelerometer in detecting motor complications
in 15 PD patients, using a self-assessment scale as gold standard. Measures for
hypokinesia, bradykinesia, and tremor showed limited sensitivity (0.60 to 0.71) and
specificity (0.66 to 0.76) for motor complications in individual PD patients. In the
group of PD patients, comparing the "on" with the "off" state yielded statistically
significant differences for tremor only. Objective dyskinesia measures correlated
with time spent with dyskinesias (r = 0.89). The authors stated that although
validated for the measurement of hypokinesia, bradykinesia, and tremor,
continuous ambulatory multi-channel accelerometer currently can not detect "on"
and "off" in individual PD patients.

In a review on accelerometer, Kavanagh and Menz (2008) noted that despite
significant progress in the use of accelerometer to evaluate gait patterns, there are
several areas of scientific and clinical importance that are yet to be fully explored:
(i) the validity of accelerometer-based approaches to motion assessment is
scarcely reported. There is considerable potential to enhance gait measurement
with accelerometers by the addition of rate gyroscopes, magnetometers and
electrogoniometers, (ii) despite the frequently cited benefit of employing
accelerometer-based gait analysis to test under "real world" conditions, few
studies have actually assessed gait patterns over extended duration, under real-
life environmental conditions. The use of accelerometer to assess gait when
negotiating various walking surfaces and other environmental challenges, both
indoors and outdoors, may improve the understanding of how subjects behave
when performing normal daily activities. Although preliminary studies have been
undertaken to evaluate gait in clinical populations, few studies have examined if
therapeutic interventions (e.g., orthoses, footwear and physiotherapy) or
pharmaceuticals (e.g., l-dopa and botulinum toxin) can aid in normalizing
acceleration patterns when walking. Given their portability and relatively
straightforward data processing requirements, accelerometers may enable more
detailed gait outcome measurement in large-scale clinical trials of patients with
balance and mobility impairments.

Burke and colleagues (2009) stated that electromyography or accelerometer can
be used to evaluate tremor frequency, rhythmicity, and amplitude in the work-up of
patients with essential tremor, but are not part of the routine evaluation.

In a systematic review of accelerometer-based measures for monitoring of physical
activity after stroke, Gebruers and colleagues (2010) evaluated the clinimetric
properties and clinical applicability of different accelerometer-based measurement
techniques in persons with stroke. A systematic search of literature was
performed using a specific search strategy by means of different electronic
Actigraphy and Accelerometry

databases until October 2008 (PubMed, EMBASE, CINAHL, Cochrane Library of Clinical Trials). A first selection was made by means of title and abstract. A second selection was performed by means of predefined inclusion criteria: (i) accelerometry in stroke population, (ii) application of accelerometry in patients with stroke including clinimetric properties. The exclusion criteria were (i) dysphagia, (ii) new engineering techniques or software alterations, (iii) secondary sources, and (iv) Case studies. The clinimetric properties and applicability of accelerometry were described based on the included publications. A total of 25 articles (4 randomized controlled trials) were included. The information of the publications was divided into (i) gait, cadence, and ambulatory activity; (ii) upper-extremity activity; and (iii) topics related to stroke other than upper or lower extremity. Accelerometry was shown to be valid and had good test-retest reliability in a large number of settings. Many studies demonstrated correlations between accelerometry and common stroke scales. Trunk movements were measured as an outcome of disturbed gait. The vertical asymmetry index especially was able to differentiate between persons with stroke and healthy controls. Persons with stroke showed less ambulatory activity, measured as steps per day, than sedentary controls. Tri-axial accelerometry was able to distinguish between varying activity levels. Upper-extremity use was lesser in persons with stroke. It was impossible to calculate a minimal clinical difference for arm use by a uni-axial accelerometer. Evidence was presented that finger-tapping and sit-to-stand measured by accelerometers could be used to define recovery from stroke. The authors concluded that the literature concerning accelerometry incorporated into stroke research is young, limiting the ability to draw consistent conclusions. Nonetheless, the available evidence suggested that accelerometers yield valid and reliable data about the physical activity of patients with stroke. They stated that more research is needed to investigate clinimetric properties like predictive value and responsiveness further before implementing accelerometry in clinical trials as an outcome for change.

Cheung et al (2011) reviewed studies that used accelerometers to classify human movements and appraised their potential to determine the activities of older patients in hospital settings. All studies that validated the use of accelerometers to classify human postural movements and mobility were included. Studies included participants from any age group. All types of accelerometers were included. Outcome measures criteria explored within the studies were comparisons of derived classifications of postural movements and mobility against those made by using observations. Based on these criteria, a total of 54 studies were selected for detailed review. Data were extracted by the first author and included characteristics of study participants, accelerometers used, body positions of device attachment, study setting, duration, methods, results, and limitations of the validation studies. The accelerometer-based monitoring technique was investigated predominantly on a small sample of healthy adult participants in a laboratory setting. Most studies applied multiple accelerometers on the sternum, wrists, thighs, and shanks of participants. Most studies collected validation data while participants performed a pre-defined standardized activity protocol. The authors concluded that accelerometer devices have the potential to monitor human movements continuously to determine postural movements and mobility for the assessment of functional ability. They stated that future studies should focus
on long-term monitoring of free daily activity of a large sample of mobility-impaired or older hospitalized patients, who are at risk for functional decline.

Bento et al (2012) reviewed the use of accelerometry as an objective measure of physical activity in adults and elderly people. A systematic review of studies on the use of accelerometry as an objective measure to assess physical activity in adults were examined in PubMed Central, Web of Knowledge, EBSCO and Medline databases from March 29 to April 15, 2010. The following keywords were used: "accelerometry," "accelerometer," "physical activity," "PA," "patterns," "levels," "adults," "older adults," and "elderly," either alone or in combination using "AND" or "OR." The reference lists of the articles retrieved were examined to capture any other potentially relevant article. Of 899 studies initially identified, only 18 were fully reviewed, and their outcome measures abstracted and analyzed.

Eleven studies were conducted in North America (United States), 5 in Europe, 1 in Africa (Cameroon) and 1 in Australia. Very few enrolled older people, and only 1 study reported the season or time of year when data were collected. The articles selected had different methods, analyses, and results, which prevented comparison between studies. The authors concluded that there is a need to standardize study methods for data reporting to allow comparisons of results across studies and monitor changes in populations. These data can help design more adequate strategies for monitoring and promotion of physical activity.

In a validity study, Item-Glattthorn et al (2012) evaluated the concurrent validity of an accelerometry-based system (IDEEA(a)) with a criterion instrument (Gaitrite(b)) for the evaluation of spatio-temporal gait variables in orthopedic patients. A total of 26 men with unilateral hip osteoarthritis (mean age +/- SD, 54 +/- 9 years) were included in this study. Patients were asked to walk at normal and fast velocities while gait cycle, swing, double support, step length, cadence and speed were concomitantly recorded with the 2 instruments. Concurrent criterion-related validity was examined using intra-class correlation coefficients and Bland-Altman limits of agreement. Intra-class correlation coefficients were acceptable for all gait parameters (range of 0.815 to 0.997), except step length (0.783). Limits of agreement were low for gait cycle, swing and cadence, though relatively high for double support, step length and speed. A significant bias between the 2 measuring instruments was consistently observed. The authors concluded that in patients with hip osteoarthritis, quantitative gait analysis with the IDEEA accelerometry system was satisfactory for the main temporal gait parameters, while double support, step length and walking speed quantifications were invalid. They stated that IDEEA should be used with caution, and modifications of the system are recommended for improved use in clinical practice and research.

The Tremorometer is a physiologic recording system using accelerometers that generates precision tremor frequency and amplitude information. Caligiuri and Tripp (2004) described the results of the Tremorometer, a hand-held device, for quantifying tremor in the upper extremity. The specific aims of the study were to evaluate: (i) the reliability of the device to record tremor frequency and amplitude; (ii) the relationship between observer ratings of tremor severity and spectral power derived from the instrument; (iii) the effects of limb posture on tremor properties recorded by the instrument; and (iv) whether scores from the instrument can discriminate types of tremor with sufficient accuracy to be of diagnostic value. Results from 242 subjects with tremor showed significant effects of limb posture...
on tremor frequency detected by the device that could not be revealed using traditional observer severity ratings. Subjects with tremor associated with idiopathic Parkinson's disease were distinguished from patients with drug-induced parkinsonian tremor with 83% accuracy. These and other findings on instrument validity demonstrated that tremor assessment can be performed using standard quantitative procedures that overcome many of the limitations inherent in subjective observer ratings. The authors concluded that the portability of the Tremorometer made it a useful tool for multi-site collaborative studies in community settings. However, there is insufficient evidence that the Tremorometer improve therapeutic responses for the purpose of decreasing tremor in patients with tremor. Well-designed studies are needed to ascertain its clinical value.

Wootton et al (2012) evaluated the validity of accelerometer data, its responsiveness to change, and the practicality and acceptability of accelerometers when used as an outcome measure in a clinical trial. This study used data collected from 336 subjects of the Softened Water Eczema Trial (SWET). Accelerometer data were compared with 3 standardized scales: (i) Six Area, Six Sign Atopic Dermatitis (SASSAD) severity score, (ii) Patient Oriented Eczema Measure (POEM), and (iii) Dermatitis Family Impact (DFI). Spearman's rank testing was used for correlations. Only 70% of trial participants had complete data, compared with 96% for the primary outcome (eczema severity - SASSAD). The convergent validity of accelerometer data with other measures of eczema severity was poor: correlation with SASSAD 0.15 (p = 0.02), and POEM 0.10 (p = 0.13). Assessing for divergent validity against quality of life measures, the correlation with the DFI was low (r = 0.29, p < 0.0001). Comparing the change scores from baseline to week 12 for SASSAD, POEM, and DFI with the change in accelerometer scores these researchers found low, negative correlations (r = -0.02, p = 0.77; r = -0.12, p = 0.06; and r = -0.01, p = 0.87, respectively). In general, the units were well tolerated, but suggestions were made that could improve their usability in children. The authors concluded that actigraphy did not correlate well with disease severity or quality of life when used as an objective outcome measure in a multi-center clinical trial, and was not responsive to change over time. They stated that further work is needed to establish why this might be, and to establish improved methods of distinguishing between eczema-related and eczema-nonrelated movements.

Epilepsy Monitoring System

For epileptic seizures, seizure frequency is the primary indicator and measure on which to base treatment (AAP, 2014). Many patients are asked to maintain seizure diaries for this purpose, but evidence has shown that the self-reported data is unreliable. Due to the high-cost of video EEG monitoring in an inpatient epilepsy monitoring unit (EMU) and the unreliability of patient paper seizure diaries, there is a need for a less costly, objective, diagnostic tool to track patient seizure count and frequency. Therefore, diagnostic event monitoring tools are being developed that are to be worn by the patient in order to capture seizure event data.

The epilepsy event monitoring system is a device that includes an adhesive patch connected to a sensor that will continuously detect and record ECG and 3-axis accelerometer motion data which communicates to a base station hub and then
notifies a caregiver (AAP, 2014). The system is being specifically developed to address the unmet need of objective, non-invasive, discrete seizure monitoring, reporting and notification.

Several clinical trials are ongoing. The Epilepsy Institute of the Netherlands Foundation (SEIN) and the University Medical Center Utrecht (UMCU) are sponsoring a clinical trial in the home environment of 60 epilepsy patients to investigate the sensitivity and positive predictive value of a multimodal sensor system (‘LivAssured’) for the detection of nocturnal motor seizures. Subjects included in this study are children and adolescents living at home, or adults with a mental impairment living in long-term care facilities, who are diagnosed with major motor seizures (defined as tonic-clonic, generalized tonic, hypermotor or series of myoclonic seizures) with minimal nocturnal motor seizure frequency (one per week). The primary outcome of the study will be the detection rate of epileptic nocturnal seizures by the combination of heart rate and accelerometry analysis and the added value of video and audio detection.

Cyberonics (2014) is conducting a pilot observational study to evaluate a prototype device designed to collect ECG and accelerometer data in children and adults with epilepsy. The investigational system is composed of a sensor, patch, hub, and caregiver application. The sensor is applied externally during periods of nocturnal sleep for up to 7 nights. Results of this study are pending. The primary outcome of the study is to collect usability data from the intended use population of people with epilepsy and their caregivers.

**CPT Codes / HCPCS Codes / ICD-9 Codes**

**CPT codes not covered for indications listed in the CPB:**

0199T Physiologic recording of tremor using accelerometer(s) and gyroscope(s), (including frequency and amplitude) including interpretation and report

95803 Actigraphy testing, recording, analysis, interpretation and report (minimum of 72 hours to 14 consecutive days of recording)

**ICD-9 codes not covered for indications listed in the CPB (not all-inclusive):**

304.00 - Opioid type dependence
304.03

309.81 Posttraumatic stress disorder

311 Depressive disorder, not elsewhere classified

332.0 Paralysis Agitans

332.1 Secondary Parkinsonism
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<th>Code</th>
<th>Description</th>
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<td>333.1</td>
<td>Essential and other specified forms of tremor</td>
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<td>Epilepsy and recurrent seizures</td>
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<td>Sleep disturbances</td>
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</table>

The above policy is based on the following references:

**Actigraphy Testing:**

43. Plante DT. Leg actigraphy to quantify periodic limb movements of sleep: A systematic review and meta-analysis. Sleep Med Rev. 2014 Feb 17 [Epub ahead of print].

Accelerometry:


Epilepsy Monitoring System


