Clinical Policy Title: Actigraphy

Clinical Policy Number: CCP.1275

Effective Date: April 1, 2017
Initial Review Date: November 16, 2016
Most Recent Review Date: November 6, 2018
Next Review Date: November 2019

Policy contains:
- Actigraphy.
- Circadian rhythm sleep disorders.
- Polysomnography.

Related policies:
CCP.1147 Diagnosing obstructive sleep apnea in adults

ABOUT THIS POLICY: Prestige Health Choice has developed clinical policies to assist with making coverage determinations. Prestige Health Choice’s clinical policies are based on guidelines from established industry sources, such as the Centers for Medicare & Medicaid Services (CMS), state regulatory agencies, the American Medical Association (AMA), medical specialty professional societies, and peer-reviewed professional literature. These clinical policies along with other sources, such as plan benefits and state and federal laws and regulatory requirements, including any state- or plan-specific definition of “medically necessary,” and the specific facts of the particular situation are considered by Prestige Health Choice when making coverage determinations. In the event of conflict between this clinical policy and plan benefits and/or state or federal laws and/or regulatory requirements, the plan benefits and/or state and federal laws and/or regulatory requirements shall control. Physicians and other health care providers are solely responsible for the treatment decisions for their patients. Prestige Health Choice’s clinical policies are for informational purposes only and not intended as medical advice or to direct treatment. Prestige Health Choice’s clinical policies are reflective of evidence-based medicine at the time of review. As medical science evolves, Prestige Health Choice will update its clinical policies as necessary. Prestige Health Choice’s clinical policies are not guarantees of payment.

Coverage policy

Prestige Health Choice considers actigraphy to be clinically proven and, therefore, medically necessary

1. To estimate sleep parameters in adult patients with insomnia disorder.
2. In the assessment of pediatric patients with insomnia disorder.
3. In the assessment of adult patients with circadian rhythm sleep-wake disorder.
4. In the assessment of pediatric patients with circadian rhythm sleep-wake disorder.
5. When integrated with home sleep apnea test devices to estimate total sleep time during recording (in the absence of alternative objective measurements of total sleep time) in adult patients suspected of sleep-disordered breathing.
6. To monitor total sleep time prior to testing with the Multiple Sleep Latency Test in adult and pediatric patients with suspected central disorders of hypersomnolence.
7. To estimate total sleep time in adult patients with suspected insufficient sleep syndrome. (Smith, 2018a).

Limitations:
Coverage determinations are subject to benefit limitations and exclusions as delineated by the state Medicaid authority. The Florida Medicaid website may be accessed at http://ahca.myflorida.com/Medicaid/.

Prestige Health Choice considers actigraphy to be investigational/experimental, and therefore not medically necessary, for all other uses, including when used in place of electromyography for the diagnosis of periodic limb movement disorder in adult and pediatric patients (Smith, 2018a).

**Alternative covered services:**

Polysomnography.

**Background**

Actigraphy is a method of continually measuring human rest and activity cycles (unit movements) through an actimetry sensor. The technique first began in the 1960s. The three main types of this device are sleep actigraphs, activity actigraphs, and movement actigraphs. Improvements in actigraphy technology include piezoelectric sensors, lithium batteries, a digital data storage (Martin, 2011).

Since the 1990s, the predominant purpose for the device is sleep behavior. Sleep actigraphs, worn on the non-dominant arm like a wristwatch often (consecutively) for a week or more, are used for disorders like insomnia, circadian rhythm sleep disorders, sleepiness, and restless leg syndrome. Unlike polysomnography, actigraphs permit movement by the patient while data is recorded. Information can be later transmitted to a computer, or can be analyzed in real time. These devices are used around the clock for days at a time (Martin, 2011).

Actigraphy is also used to measure activity behavior. Activity actigraphs are worn like a pedometer around the waist. They are used for several days and evaluate activities while awake, plus calories burned. Activity actigraphs are preferable for measuring and assessing activities during waking hours rather than sleep.

A third type of actigraphy is used to measure human movement. Movement actigraphs are larger than sleep or activity actigraphs, and are worn on the dominant shoulder. These actigraphs are three dimensional (the others are one-dimensional), and are used only for several hours at a time (John, 2012).

The actigraph unit has an accelerometer, a low-pass filter which filters out all but the 2-3 Hz band to ignore external vibrations; a timer for starting and stopping, a memory to store data, and an interface to program the timer and download data.

**Searches**
Prestige Health Choice searched PubMed and the databases of:

- UK National Health Services Centre for Reviews and Dissemination.
- Agency for Healthcare Research and Quality’s National Guideline Clearinghouse and other evidence-based practice centers.
- The Centers for Medicare & Medicaid Services.

We conducted searches on August 29, 2018. Search term was: “Actigraphy.”

We included:

- **Systematic reviews**, which pool results from multiple studies to achieve larger sample sizes and greater precision of effect estimation than in smaller primary studies. Systematic reviews use predetermined transparent methods to minimize bias, effectively treating the review as a scientific endeavor, and are thus rated highest in evidence-grading hierarchies.
- **Guidelines based on systematic reviews.**
- **Economic analyses**, such as cost-effectiveness, and benefit or utility studies (but not simple cost studies), reporting both costs and outcomes — sometimes referred to as efficiency studies — which also rank near the top of evidence hierarchies.

**Findings**

The American Sleep Disorders Association initially did not endorse actigraphy in the routine assessment of sleep disorders, but as a potential adjunct in some cases (Thorpy, 1995). In 2007, the American Academy of Sleep Medicine published a guideline stating actigraphy is indicated to evaluate patients with advanced sleep phase syndrome, delayed sleep phase syndrome, and shift work disorder. The panel added that “some evidence” existed for actigraphy’s ability to evaluate other conditions, such as jet lag disorder and non-24 hour sleep/wake syndrome (Morganthaler, 2007).

In 2012, the American Association of Sleep Technologists listed the same criteria for actigraphy use in the 2007 guideline, along with evaluating circadian rhythm patterns and sleep disturbances in patients with insomnia or hypersomnia (American Association of Sleep Technologists, 2012). A 2015 Society of Behavioral Sleep Medicine guideline asserted actigraphy is easier to use, and less expensive and cumbersome than polysomnography, the gold standard for sleep recording, adding actigraphy can augment polysomnography data when an overnight sleep study is indicated, as it can be used at home (Ancoli-Israel, 2015).

A recent guideline from the American Academy of Sleep Medicine recommended that, in cases of suspected sleep apnea, after excluding conditions such as significant cardiovascular disease, respiratory muscle weakness, high risk of hypoventilation, chronic opioid use, history of stroke, actigraphy can be used as part of a home sleep apnea test (Kapur, 2017). The most recent (July, 2018) American Academy
of Sleep Medicine guideline for actigraphy lists seven specific conditions for which the test is considered necessary; see coverage section on page one for these conditions (Smith, 2018a).

Early studies tended to agree that actigraphy was not as accurate in determining sleep measurements as polysomnography, but was more reliable than sleep logs that rely on patients recalling how often and for how long they remained awake during the night (Ancoli-Israel, 2003).

The following systematic reviews and/or meta-analyses have provided information on the ability of actigraphy to accurately measure sleep parameters, time, norms, and abnormalities:

1. **Academy Task Force.** A meta-analysis of 81 studies served as the basis for the American Academy of Sleep Medicine’s July 2018 guideline. The meta-analysis was conducted by an Academy task force, which assessed four general areas of evidence, including 1) quality of evidence, 2) benefits versus harms, 3) patient values and preferences, and 4) resource use. Data from the studies demonstrate that actigraphy provides useful and often unique data for some sleep parameters in patients with suspected or diagnosed insomnia, circadian rhythm sleep-wake disorders, sleep-disordered breathing, central disorders of hypersomnolence, and adults with insufficient sleep syndrome. (Smith, 2018b).

2. **Comparison with Polysomnography.** Actigraphy is an objective measure, and produces similar or better results than subjective measures such as sleep diaries and questionnaires (Geiger-Brown, 2015). A review of 14 studies concluded that accuracy of sleep monitoring measurement using actigraphy and polysomnography is comparable (Martin, 2011). However, a systematic review of 14 studies notes that actigraphy results can be heterogenous, and thus must be improved before replacing polysomnography (Plante, 2014).

3. **Comparison with Polysomnography (Portable Monitoring).** Some studies have upheld the comparable ability of portable monitoring (which included actigraphy) and polysomnography to diagnose obstructive sleep apnea. In one trial of 106 patients, statistically similar outcomes were observed for mean nightly adherence, decrease in Epworth Sleepiness Scale score, improvement in the global Functional Outcome of Sleep Questionnaire score, and continuous positive airway pressure satisfaction (Berry, 2008). A study of 31 pregnant women in their 3rd trimester were tested using both ambulatory polysomnography and the Watch-PAT device that includes actigraphy. Statistically similar outcomes were produced in apnea-hypopnea index, respiratory disturbance index, mean oxygen saturation, and minimum oxygen saturation, each \( P < 0.001 \) (O’Brien, 2012).

4. **Determining Differences Between Bipolar and non-Bipolar.** A 2015 meta-analysis of nine studies compared the diagnostic ability of actigraphy in 412 persons with or without bipolar disorders. Actigraphy was found to detect significant differences between the two groups in sleep latency, sleep duration, wake after sleep onset, and sleep efficiency. Differences were greatest when age
differences between cases and controls were larger, indicating that future actigraphy studies should better match groups by age (Geoffroy, 2015).

Another meta-analysis/systematic review of sleep-wake disturbance in patients with bipolar disorder and patients at high risk for the disease found higher averages for bipolar patients versus controls for total sleep time, sleep onset latency, time in bed, and wake after sleep onset (using actigraphy). Compared with adults with insomnia, bipolar patients had longer total sleep time and lower activity counts, based on activity results. Persons at risk for bipolar disorder versus healthy controls had lower relative amplitude of the sleep-wake cycle and lower variability in sleep efficiency. (Ng, 2015).

5. **Measuring Sleep and Activity in Attention Deficit Hyperactivity Disorder.** Another meta-analysis (eight articles, n=393) used actigraphy as a means of measuring total sleep time and daytime activity in childhood Attention Deficit Hyperactivity Disorder patients who did or did not receive methylphenidate, finding that the drug reduced mean activity time in children with Attention Deficit Hyperactivity Disorder but also negatively affected total sleep time (DeCrescenzo, 2014). Members of the same research group later declared actigraphy to be an effective tool in monitoring sleep and activity in Attention Deficit Hyperactivity Disorder (DeCrescenzo, 2016), and in monitoring sleep and activity in bipolar disorders, in a systematic review of 13 studies and 821 patients (DeCrescenzo, 2017).

6. **Sleep Disturbances in Patients with Certain Disorders.** Actigraphy has been used to measure sleep disturbances for patients with specific disorders. Systematic reviews have focused on actigraphy to understand sleep patterns in breast cancer patients undergoing chemotherapy (Madsen, 2015), patients with Alzheimer’s disease (Camargos, 2013), depression (Burton, 2013), and post-surgical patients (Madsen, 2013).

7. **Measuring Sleep Through Leg Activity.** Leg actigraphy to analyze periodic limb movements of sleep was a topic of a meta-analysis of 14 studies. The study concluded that polysomnography is the most effective means of understanding these abnormalities. While actigraphy shows promise, results are difficult to compare between studies, since they vary in sensitivity and specificity to detect the disorder (often due to the multiple actigraphy models); and comparing actigraph data placed on both legs also can be inaccurate (Plante, 2014).

8. **Post-Surgical Patients.** A large systematic review, based on 32 studies, found that actigraphy can provide accurate and useful data on for post-surgical patients, including total sleep time/sleep efficiency reduction, increase in awakenings, differentiation between delirious and non-delirious patients, ability to determine differential effects based on patient age, and ability to document reduced severity in patients after minor surgery (Madsen, 2013).
9. **Pediatric Nighttime Sleep.** A systematic review/meta-analysis of 79 articles used actigraphy to determine average sleep duration steadily declined from 9.68 to 7.4 hours between ages 3-5 and 15-18. Sleep latency was consistent at 19.4 minutes per night, and 1-2 hours less on weekend or non-school days (Galland, 2018).

Randomized controlled trials have compared actigraphy with other methods of detecting sleep and other human movements. A recent study of 78 children with sleep disorders revealed actigraphy produced comparable results to polysomnography, and superior to those of a smartphone application accelerometer named MotionX 24/7 (Toon, 2016). A trial involving 11 healthy subjects found actigraphy provided useful assessments of sleep, but was not as effective as polysomnography in assessing direct activity endpoints (Peterson, 2012).

**Policy updates:**

A total of two guidelines/other and one peer-reviewed reference were added to, this policy, and two guidelines/other removed from this policy in August, 2018.

**Summary of clinical evidence:**

<table>
<thead>
<tr>
<th>Citation</th>
<th>Content, Methods, Recommendations</th>
</tr>
</thead>
<tbody>
<tr>
<td>Geoffroy (2015)</td>
<td>Assessment of difference in sleep abnormalities between bipolar patients and controls, using actigraphy</td>
</tr>
</tbody>
</table>
| Key points:          | Meta-analysis of nine studies (n=412).  
|                      | Found bipolar patients (versus. controls) were significantly different in sleep latency, sleep duration, wake after sleep onset, and sleep efficiency.  
|                      | Greater differences when age differences between groups were greatest suggests that future studies should better control for age. |
| Ng (2015)            | Comparing sleep-wake disturbances in bipolar and at-risk persons with controls |
| Key points:          | Meta-analysis of 21 studies, n=531, actigraphy was one of the tests used; and found  
|                      | - Longer times for bipolar patients versus. controls for total sleep time, sleep onset latency, time in bed, and wake after sleep onset.  
|                      | - Longer sleep time and lower activity counts based on activity results for bipolar patients versus adults with insomnia.  
|                      | - Lower relative amplitude of the sleep-wake cycle and lower variability in sleep efficiency for persons at high risk for bipolar patients versus controls. |
| DeCrescenzo (2014)   | Using actigraphy to monitor effects of methylphenidate, children w/ Attention Deficit Hyperactivity Disorder |
| Key points:          | Meta-analysis, eight articles (n=393), children with Attention Deficit Hyperactivity Disorder, taking methylphenidate or placebo.  
|                      | Cases have lower average activity than controls, lower total sleep time.  
|                      | Actigraphy was able to detect the above differences. |
| Madsen (2013)        | Assessment of ability of |
| Key points:          | Systematic review, 32 studies included. |
Actigraphy to document sleep changes for postsurgical patients

- Actigraphy able to document reduction in total sleep time, reduction in sleep efficiency, increase in awakenings, differentiation between delirious and non-delirious patients, differentiation of detrimental effects based on patient age, reduced severity for minor (versus major) surgery.

References

Professional society guidelines/other:


Peer-reviewed references:


**Centers for Medicare & Medicaid National Coverage Determinations:**

No National Coverage Determinations identified as of the writing of this policy.

**Local Coverage Determinations:**

No Local Coverage Determinations identified as of the writing of this policy.

**Commonly submitted codes**

Below are the most commonly submitted codes for the service(s)/item(s) subject to this policy. This is not an exhaustive list of codes. Providers are expected to consult the appropriate coding manuals and bill accordingly.
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