Introduction

Actigraphy is the recording of how a body moves. Actigraphy uses a small device that is usually placed on the wrist or ankle. In some cases the device is placed on a leg to assess restless legs syndrome. It also has been used to try to look at a person’s sleep-wake cycles. High quality medical studies do not show that actigraphy works as well as or better than the usual ways of determining sleep-wake cycles. For this reason, actigraphy is considered investigational (unproven).

Note: The Introduction section is for your general knowledge and is not to be taken as policy coverage criteria. The rest of the policy uses specific words and concepts familiar to medical professionals. It is intended for providers. A provider can be a person, such as a doctor, nurse, psychologist, or dentist. A provider also can be a place where medical care is given, like a hospital, clinic, or lab. This policy informs them about when a service may be covered.

Policy Coverage Criteria

<table>
<thead>
<tr>
<th>Service</th>
<th>Investigational</th>
</tr>
</thead>
<tbody>
<tr>
<td>Actigraphy</td>
<td>Actigraphy is considered investigational when used as the sole technique to record and analyze body movement, including</td>
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</tbody>
</table>


### Service

<table>
<thead>
<tr>
<th>Investigational</th>
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<td>but not limited to its use to evaluate sleep disorders.</td>
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**Note:** This does not include the use of actigraphy as a component of portable sleep monitoring.

### Coding

<table>
<thead>
<tr>
<th>Code</th>
<th>Description</th>
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<tbody>
<tr>
<td>CPT</td>
<td></td>
</tr>
<tr>
<td>95803</td>
<td>Actigraphy testing, recording, analysis, interpretation and report (minimum of 72 hours to 14 consecutive days of recording)</td>
</tr>
</tbody>
</table>

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### Related Information

N/A

### Evidence Review

### Description

Actigraphy refers to the assessment of body movement activity patterns using devices, typically placed on the wrist or ankle, during sleep, which are interpreted by computer algorithms as periods of sleep and wake. Sleep-wake cycles may be altered in sleep disorders, including insomnia and circadian rhythm sleep disorders. Also, actigraphy could be used to assess sleep/wake disturbances associated with other disorders.
Background

Sleep Disorders

Sleep disorders affect a large percentage of the U.S. population. For example, estimates suggest that 15% to 24% of the U.S. population suffers from insomnia. Lack of sleep also contributes reduced cognitive functioning, susceptibility to heart disease, and workplace absenteeism.

Diagnosis

Actigraphy refers to the assessment of activity patterns (body movement) using devices, typically placed on the wrist or ankle, which are interpreted by computer algorithms as periods of sleep (absence of activity) and wake (activity). Actigraphy devices are typically placed on the nondominant wrist with a wristband and are worn continuously for at least 24 hours. Activity is usually recorded for a period of 3 days to 2 weeks but can be collected continuously over extended periods with regular downloading of data onto a computer. The activity monitors may also be placed on the ankle to assess restless legs syndrome or on the trunk to record movement in infants.

The algorithms for detecting movement vary across devices and may include “time above threshold,” the “zero crossing method” (the number of times per epoch that activity level crosses zero), or “digital integration” method, resulting in different sensitivities. Sensitivity settings (eg, low, medium, high, automatic) can also be adjusted during data analysis. The most commonly used method (digital integration) reflects both acceleration and amplitude of movement.

Data on patient bed times (lights out) and rise times (lights on) are usually entered into the computer from daily patient sleep logs or by patient-activated event markers. Proprietary software is then used to calculate periods of sleep based on the absence of detectable movement, along with movement-related level of activity and periods of wake. In addition to providing graphic depiction of the activity pattern, the device-specific software can then analyze and report a variety of sleep parameters, including sleep onset, sleep offset, sleep latency, total sleep duration, and wake after sleep onset (actigraphy could also be used to measure the level of a person’s physical activity).

Actigraphy has been used for more than 2 decades as an outcome measure in sleep disorders research. For clinical applications, actigraphy is being evaluated as a measure of sleep-wake cycles in sleep disorders, including insomnia and circadian rhythm sleep disorders. Also, actigraphy is being investigated as a measure of sleep-wake disturbances associated with other diseases and disorders.
Summary of Evidence

For individuals who have circadian sleep-wake rhythm disorders who receive actigraphy the evidence includes ancillary study within a randomized controlled trial. Relevant outcomes are test accuracy and test validity. Comparison with PSG has shown that actigraphy is limited in differentiating between sleep and wake in more disturbed sleep. Actigraphy appears to reliably measure sleep onset and total sleep time in some patient populations. Comparisons with PSG and sleep diaries are limited. Evidence has shown that actigraphy does not provide a reliable measure of sleep efficiency in this patient population. The evidence is insufficient to determine the effects of the technology on health outcomes.

For children and adolescents with sleep-associated disorders in children and adolescents who receive actigraphy the evidence includes prospective and retrospective validation studies. Relevant outcomes are test accuracy and validity. Comparisons with PSG have shown that actigraphy can differ significantly in its estimations of wake and sleep times and sleep onset latency. Comparisons with sleep diaries have also failed to show satisfactory agreement, with greater discrepancies for more disturbed sleep. Evidence has shown that actigraphy does not provide a reliable measure of sleep efficiency in this patient population. The evidence is insufficient to determine the effects of the technology on health outcomes.

For individuals who have central disorders of hypersomnolence who receive actigraphy the evidence includes a comparative observational study. Relevant outcomes are test accuracy and validity. Comparison with video-PSG has indicated that actigraphy has a sensitivity of 26.1% and specificity of 95.5%. General evidence has also revealed that the accuracy of actigraphy for differentiating between wake and sleep decreases as the level of sleep disturbance increases. Although actigraphy appears to provide reliable measures of sleep onset and wake time in some patient populations, its clinical utility compared with that of sleep diaries has not been demonstrated. Evidence has shown that actigraphy does not provide a reliable measure of sleep efficiency in this patient population. The complexity of the various syndromes as well as the potential for medical treatment with significant adverse events makes accurate diagnosis essential. The evidence is insufficient to determine the effects of the technology on health outcomes.

For individuals who have insomnia who receive actigraphy the evidence includes prospective and retrospective validation studies. Relevant outcomes are test accuracy and validity. Comparisons with PSG have shown that actigraphy has poor agreement for reporting wake time and can overestimate sleep efficiency. Comparison with sleep diaries has indicated that actigraphy is less effective at differentiating between patients with insomnia and controls.
General evidence has also revealed that the accuracy of actigraphy for differentiating between wake and sleep decreases as the level of sleep disturbance increases. Although actigraphy appears to provide reliable measures of sleep onset and wake time in some patient populations, its clinical utility compared with sleep diaries has not been demonstrated. Evidence has shown that actigraphy does not provide a reliable measure of sleep efficiency in this patient population. The evidence is insufficient to determine the effects of the technology on health outcomes.

Ongoing and Unpublished Clinical Trials

A search of ClinicalTrials.gov in May 2018 did not identify any ongoing or unpublished trials that would likely influence this review.

Practice Guidelines and Position Statements

American Academy of Sleep Medicine

The American Academy of Sleep Medicine updated its 2007 practice parameters in 2015 on the use of actigraphy for the assessment of sleep and sleep disorders as well as circadian rhythm sleep disorders (see Table 1).18-20

Table 1. Recommendations for Actigraphy

<table>
<thead>
<tr>
<th>Condition</th>
<th>Actigraphy for Diagnosis</th>
<th>Actigraphy to Measure Treatment Response</th>
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<tbody>
<tr>
<td>Shift work disorder</td>
<td>Indicated (option)</td>
<td>Indicated (guideline)</td>
</tr>
<tr>
<td>Jet lag disorder</td>
<td>Not routinely indicated (option)</td>
<td>Indicated (guideline)</td>
</tr>
<tr>
<td>Advanced sleep phase disorder</td>
<td>Indicated (guideline)</td>
<td>Indicated (guideline)</td>
</tr>
<tr>
<td>Delayed sleep phase disorder</td>
<td>Indicated (guideline)</td>
<td>Indicated (guideline)</td>
</tr>
<tr>
<td>Free running disorder</td>
<td>Indicated (option)</td>
<td>Indicated (guideline)</td>
</tr>
<tr>
<td>Irregular sleep-wake rhythm</td>
<td>Indicated (option)</td>
<td>Indicated (guideline)</td>
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</table>

“Standards” describe a generally accepted patient care strategy, which reflects a high degree of clinical certainty. “Guidelines” reflect a moderate degree of clinical certainty. “Options” imply either inconclusive or conflicting evidence or conflicting expert opinion.

AASM: American Academy of Sleep Medicine.
The American Academy of Sleep Medicine practice parameters from 2008 evaluated the clinical management of chronic insomnia in adults, stating that actigraphy is indicated as a method (option) to characterize circadian rhythm patterns or sleep disturbances in individuals with insomnia, including insomnia associated with depression.21

Medicare National Coverage

There is no national coverage determination. In the absence of a national coverage determination, coverage decisions are left to the discretion of local Medicare carriers.

Regulatory Status

Numerous actigraphy devices have been cleared for marketing by the U.S. Food and Drug Administration 510(k) process. Some actigraphy devices are designed and marketed to measure sleep-wake states while others to measure levels of physical activity.

Food and Drug Administration product code: OLV.

References


<table>
<thead>
<tr>
<th>Date</th>
<th>Comments</th>
</tr>
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<tbody>
<tr>
<td>11/13/07</td>
<td>Replace Policy - Policy reviewed with literature search; references added; no change in policy statement.</td>
</tr>
<tr>
<td>01/13/09</td>
<td>Code Update - Code 95803 added, effective 1/1/09.</td>
</tr>
<tr>
<td>10/13/09</td>
<td>Replace Policy - Policy reviewed with literature search; references added; no change in policy statement.</td>
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<tr>
<td>05/10/11</td>
<td>Replace Policy - Policy updated with literature review through December 2010; references added and reordered; policy statement unchanged.</td>
</tr>
<tr>
<td>04/10/12</td>
<td>Replace policy. Policy updated with literature review through November 2011; references 10 and 12 added and references reordered; some references removed. Policy statement unchanged.</td>
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<td>12/4/12</td>
<td>Updated Related Policy title, 2.01.503.</td>
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<tr>
<td>04/16/13</td>
<td>Replace policy. Rationale section updated based on a literature review through January 4, 2013. References 8 and 15 added; others renumbered or removed. Policy statement unchanged.</td>
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<td>10/16/13</td>
<td>Update Related Policies. Change title to policy 2.01.503.</td>
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<tr>
<td>05/05/14</td>
<td>Annual Review. Policy updated with literature review through January 6, 2014; references 7, 10, 12, 15, 18, and 25 added; policy statement unchanged. ICD-9 and ICD-10 diagnosis and procedure codes removed; they are not utilized in adjudication.</td>
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<td>11/20/15</td>
<td>Update Related Policies. Remove 7.01.516.</td>
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<tr>
<td>12/01/16</td>
<td>Annual Review, approved November 8, 2016. Policy reviewed with literature search; No new studies were identified that compared actigraphy with other diagnostic methods; no change in policy statement.</td>
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<tr>
<td>01/01/18</td>
<td>Minor update; removed 2.01.503 from Related Policies as it was archived.</td>
</tr>
<tr>
<td>09/01/18</td>
<td>Annual Review, approved August 10, 2018. Policy updated with literature review through April 2018; references 1 and 20 added. Policy statement unchanged.</td>
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</table>

**Disclaimer:** This medical policy is a guide in evaluating the medical necessity of a particular service or treatment. The Company adopts policies after careful review of published peer-reviewed scientific literature, national guidelines and local standards of practice. Since medical technology is constantly changing, the Company reserves the right to review
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Premera:
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  - Written information in other formats (large print, audio, accessible electronic formats, other formats)
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  - Qualified interpreters
  - Information written in other languages

If you need these services, contact the Civil Rights Coordinator.

If you believe that Premera has failed to provide these services or discriminated in another way on the basis of race, color, national origin, age, disability, or sex, you can file a grievance with:
Civil Rights Coordinator - Complaints and Appeals
PO Box 91102, Seattle, WA 98111
Toll free 855-332-4535, Fax 425-918-5592, TTY 800-842-5357
Email AppealsDepartmentinquines@Premera.com

You can file a grievance in person or by mail, fax, or email. If you need help filing a grievance, the Civil Rights Coordinator is available to help you.

You can also file a civil rights complaint with the U.S. Department of Health and Human Services, Office for Civil Rights, electronically through the Office for Civil Rights Complaint Portal, available at https://ocrportal.hhs.gov/ocr/portal/lobby.jsf, or by mail or phone at:
U.S. Department of Health and Human Services
200 Independence Avenue SW, Room 509F, HHH Building
Washington, D.C. 20201, 1-800-368-1019, 800-537-7697 (TDD)
Complaint forms are available at

Getting Help in Other Languages

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800-722-1471 (TTY: 800-842-5357)

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Deutsche (German):

Hmoob (Hmong):

Ilokó (Ilocano):
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Italiano (Italian):