

EVIDENCE-BASED CRITERIA SECTION: MEDICINE

ORIGINAL EFFECTIVE DATE: 09/19/22
LAST REVIEW DATE: 08/06/24
CURRENT EFFECTIVE DATE: 08/06/24
LAST CRITERIA REVISION DATE: 08/01/23
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NEXT ANNUAL REVIEW DATE: 3RD QTR 2025

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Non-Discrimination Statement and Multi-Language Interpreter Services information are located at the end of this document.

Coverage for services, procedures, medical devices and drugs are dependent upon benefit eligibility as outlined in the member's specific benefit plan. This Evidence-Based Criteria must be read in its entirety to determine coverage eligibility, if any.

This Evidence-Based Criteria provides information related to coverage determinations only and does not imply that a service or treatment is clinically appropriate or inappropriate. The provider and the member are responsible for all decisions regarding the appropriateness of care. Providers should provide BCBSAZ complete medical rationale when requesting any exceptions to these quidelines.

The section identified as "<u>Description</u>" defines or describes a service, procedure, medical device or drug and is in no way intended as a statement of medical necessity and/or coverage.

The section identified as "<u>Criteria</u>" defines criteria to determine whether a service, procedure, medical device or drug is considered medically necessary or experimental or investigational.

State or federal mandates, e.g., FEP program, may dictate that any drug, device or biological product approved by the U.S. Food and Drug Administration (FDA) may not be considered experimental or investigational and thus the drug, device or biological product may be assessed only on the basis of medical necessity.

Evidence-Based Criteria are subject to change as new information becomes available.

For purposes of this Evidence-Based Criteria, the terms "experimental" and "investigational" are considered to be interchangeable.

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Description:

This policy does not address the use of actigraphy as a component of portable sleep monitoring.

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.

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 to 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 usually 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 the "digital integration" method, resulting indifferent sensitivities. Sensitivity settings (e.g., 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 individual bedtimes (lights out) and rise times (lights on) are usually entered into the computer from daily individual sleep logs or by individual-activated event markers. Proprietary software is then used to calculate periods of sleep based on the absence of detectable movement, along with the movement-related level of activity and periods of wake. In addition to providing a 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 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.

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Criteria:

- Actigraphy when used as the sole technique to record and analyze body movement to evaluate sleep disorders is considered experimental or investigational when any ONE or more of the following criteria are met:
 - 1. Lack of final approval from the appropriate governmental regulatory bodies (e.g., Food and Drug Administration); or
 - 2. Insufficient scientific evidence to permit conclusions concerning the effect on health outcomes; or
 - 3. Insufficient evidence to support improvement of the net health outcome; or
 - 4. Insufficient evidence to support improvement of the net health outcome as much as, or more than, established alternatives; or
 - Insufficient evidence to support improvement outside the investigational setting.

Resources:

Literature reviewed 08/01/23. We do not include marketing materials, poster boards and non-published literature in our review.

- 1. Bélanger M, Bernier A, Paquet J, Simard V, Carrier J. Validating actigraphy as a measure of sleep for preschool children. *J Clin Sleep Med*. Jul 15 2013;9(7):701-6. doi:10.5664/jcsm.2844
- Dick R, Penzel T, Fietze I, Partinen M, Hein H, Schulz J. AASM standards of practice compliant validation of actigraphic sleep analysis from SOMNOwatch™ versus polysomnographic sleep diagnostics shows high conformity also among subjects with sleep disordered breathing. *Physiol Meas*. Dec 2010;31(12):1623-33. doi:10.1088/0967-3334/31/12/005
- 3. Enomoto M, Kitamura S, Nakazaki K. Validity of an algorithm for determining sleep/wake states using FS-760 in school-aged children. *J Physiol Anthropol*. Aug 18 2022;41(1):29. doi:10.1186/s40101-022-00303-2
- 4. Ford ES, Cunningham TJ, Giles WH, Croft JB. Trends in insomnia and excessive daytime sleepiness among U.S. adults from 2002 to 2012. *Sleep Med.* Mar 2015;16(3):372-8. doi:10.1016/j.sleep.2014.12.008
- 5. Hyde M, O'Driscoll DM, Binette S, et al. Validation of actigraphy for determining sleep and wake in children with sleep disordered breathing. *J Sleep Res.* Jun 2007;16(2):213-6. doi:10.1111/j.1365-2869.2007.00588.x
- 6. Insana SP, Gozal D, Montgomery-Downs HE. Invalidity of one actigraphy brand for identifying sleep and wake among infants. *Sleep Med*. Feb 2010;11(2):191-6. doi:10.1016/j.sleep.2009.08.010



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- 7. Kaplan KA, Talbot LS, Gruber J, Harvey AG. Evaluating sleep in bipolar disorder: comparison between actigraphy, polysomnography, and sleep diary. *Bipolar Disord*. Dec 2012;14(8):870-9. doi:10.1111/bdi.12021
- 8. Levenson JC, Troxel WM, Begley A, et al. A quantitative approach to distinguishing older adults with insomnia from good sleeper controls. *J Clin Sleep Med*. Feb 1 2013;9(2):125-31. doi:10.5664/jcsm.2404
- 9. Louter M, Arends JB, Bloem BR, Overeem S. Actigraphy as a diagnostic aid for REM sleep behavior disorder in Parkinson's disease. *BMC Neurol*. Apr 6 2014;14:76. doi:10.1186/1471-2377-14-76
- 10. Marino M, Li Y, Rueschman MN, et al. Measuring sleep: accuracy, sensitivity, and specificity of wrist actigraphy compared to polysomnography. *Sleep*. Nov 1 2013;36(11):1747-55. doi:10.5665/sleep.3142
- 11. Meltzer LJ, Wong P, Biggs SN, et al. Validation of Actigraphy in Middle Childhood. *Sleep*. Jun 1 2016;39(6):1219-24. doi:10.5665/sleep.5836
- 12. O'Driscoll DM, Foster AM, Davey MJ, Nixon GM, Horne RS. Can actigraphy measure sleep fragmentation in children? *Arch Dis Child*. Dec 2010;95(12):1031-3. doi:10.1136/adc.2009.166561
- 13. Paquet J, Kawinska A, Carrier J. Wake detection capacity of actigraphy during sleep. *Sleep*. Oct 2007;30(10):1362-9. doi:10.1093/sleep/30.10.1362
- 14. Short MA, Gradisar M, Lack LC, Wright H, Carskadon MA. The discrepancy between actigraphic and sleep diary measures of sleep in adolescents. *Sleep Med*. Apr 2012;13(4):378-84. doi:10.1016/j.sleep.2011.11.005
- 15. Sivertsen B, Omvik S, Havik OE, et al. A comparison of actigraphy and polysomnography in older adults treated for chronic primary insomnia. *Sleep*. Oct 2006;29(10):1353-8. doi:10.1093/sleep/29.10.1353
- 16. Smith MT, McCrae CS, Cheung J, et al. Use of Actigraphy for the Evaluation of Sleep Disorders and Circadian Rhythm Sleep-Wake Disorders: An American Academy of Sleep Medicine Clinical Practice Guideline. *J Clin Sleep Med.* Jul 15 2018;14(7):1231-1237. doi:10.5664/jcsm.7230
- 17. Spruyt K, Gozal D, Dayyat E, Roman A, Molfese DL. Sleep assessments in healthy school-aged children using actigraphy: concordance with polysomnography. *J Sleep Res.* Mar 2011;20(1 Pt 2):223-32. doi:10.1111/j.1365-2869.2010.00857.x
- 18. Taibi DM, Landis CA, Vitiello MV. Concordance of polysomnographic and actigraphic measurement of sleep and wake in older women with insomnia. *J Clin Sleep Med*. Mar 15 2013;9(3):217-25. doi:10.5664/jcsm.2482



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19. Werner H, Molinari L, Guyer C, Jenni OG. Agreement rates between actigraphy, diary, and questionnaire for children's sleep patterns. *Arch Pediatr Adolesc Med.* Apr 2008;162(4):350-8. doi:10.1001/archpedi.162.4.350

20. Yavuz-Kodat E, Reynaud E, Geoffray MM, et al. Validity of Actigraphy Compared to Polysomnography for Sleep Assessment in Children With Autism Spectrum Disorder. *Front Psychiatry*. 2019;10:551. doi:10.3389/fpsyt.2019.00551

Coding:

CPT: 95803

<u>History</u> :	<u>Date</u> :	Activity:
Medical Policy Panel Medical Director (Dr. Raja) Medical Policy Panel Medical Policy Panel	08/06/24 07/18/24 08/01/23 08/30/22	Review with no revisions Review with no revisions Review with revisions Approved guideline (Effective 9/19/22)

Policy Revisions:

08/01/23	Added:	"Insufficient evidence to support improvement of the net health outcome; or", and "Insufficient evidence to support improvement of the net health outcome as much as, or more than, established alternatives, or" to experimental or investigational criteria
08/01/23	Revised:	"Insufficient evidence to support improvement outside the investigational setting" from #3 to #5 in experimental or investigational criteria
08/01/23	Updated:	Resources section

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Non-Discrimination Statement:

Blue Cross Blue Shield of Arizona (BCBSAZ) complies with applicable Federal civil rights laws and does not discriminate on the basis of race, color, national origin, age, disability or sex. BCBSAZ provides appropriate free aids and services, such as qualified interpreters and written information in other formats, to people with disabilities to communicate effectively with us. BCBSAZ also provides free language services to people whose primary language is not English, such as qualified interpreters and information written in other languages. If you need these services, call (602) 864-4884 for Spanish and (877) 475-4799 for all other languages and other aids and services.

If you believe that BCBSAZ 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: BCBSAZ's Civil Rights Coordinator, Attn: Civil Rights Coordinator, Blue Cross Blue Shield of Arizona, P.O. Box 13466, Phoenix, AZ 85002-3466, (602) 864-2288, TTY/TDD (602) 864-4823, crc@azblue.com. You can file a grievance in person or by mail or email. If you need help filing a grievance BCBSAZ's 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, DC 20201, 1-800-368-1019, 800-537-7697 (TDD). Complaint forms are available at http://www.hhs.gov/ocr/office/file/index.html

Multi-Language Interpreter Services:

Spanish: Si usted, o alguien a quien usted está ayudando, tiene preguntas acerca de Blue Cross Blue Shield of Arizona, tiene derecho a obtener ayuda e información en su idioma sin costo alguno. Para hablar con un intérprete, llame al 602-864-4884.

Navajo: Díí kwe'é atah nílínigíí Blue Cross Blue Shield of Arizona haada yit'éego bína'ídíłkidgo éí doodago Háida bíjá anilyeedígíí ťáadoo le'é yína'ídífkidgo beehaz'áanii hólo díí ťáá hazaadk'ehjí háká a'doowołgo bee haz'ą doo baah ílínígóó. Ata' halne'ígíí koj; bich'j' hodíilnih 877-475-4799.

Chinese: 如果您,或是您正在協助的對象,有關於插入項目的名稱 Blue Cross Blue Shield of Arizona 方面的問 題,您有權利免費以您的母語得到幫助和訊息。洽詢一位翻譯員,請撥電話 在此插入數字 877-475-4799。

Vietnamese: Nếu quý vị, hay người mà quý vị đang giúp đỡ, có câu hỏi về Blue Cross Blue Shield of Arizona quý vị sẽ có quyền được giúp và có thêm thông tin bằng ngôn ngữ của mình miễn phí. Để nói chuyện với một thông dịch viên, xin goi 877-475-4799.

إن كان لديك أو لدى شخص تساعده أسئلة بخصوص Blue Cross Blue Shield of Arizona، فلديك الحق في الحصول على المساعدة والمعلومات الضرورية بلغتك من دون اية تكلفة التحدث مع مترجم اتصل ب .479-475-877



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Multi-Language Interpreter Services:

Tagalog: Kung ikaw, o ang iyong tinutulangan, ay may mga katanungan tungkol sa Blue Cross Blue Shield of Arizona, may karapatan ka na makakuha ng tulong at impormasyon sa iyong wika ng walang gastos. Upang makausap ang isang tagasalin, tumawag sa 877-475-4799.

Korean: 만약 귀하 또는 귀하가 돕고 있는 어떤 사람이 Blue Cross Blue Shield of Arizona 에 관해서 질문이 있다면 귀하는 그러한 도움과 정보를 귀하의 언어로 비용 부담없이 얻을 수 있는 권리가 있습니다. 그렇게 통역사와 얘기하기 위해서는 877-475-4799 로 전화하십시오.

French: Si vous, ou quelqu'un que vous êtes en train d'aider, a des questions à propos de Blue Cross Blue Shield of Arizona, vous avez le droit d'obtenir de l'aide et l'information dans votre langue à aucun coût. Pour parler à un interprète, appelez 877-475-4799.

German: Falls Sie oder jemand, dem Sie helfen, Fragen zum Blue Cross Blue Shield of Arizona haben, haben Sie das Recht, kostenlose Hilfe und Informationen in Ihrer Sprache zu erhalten. Um mit einem Dolmetscher zu sprechen, rufen Sie bitte die Nummer 877-475-4799 an.

Russian: Если у вас или лица, которому вы помогаете, имеются вопросы по поводу Blue Cross Blue Shield of Arizona, то вы имеете право на бесплатное получение помощи и информации на вашем языке. Для разговора с переводчиком позвоните по телефону 877-475-4799.

Japanese: ご本人様、またはお客様の身の回りの方でも、Blue Cross Blue Shield of Arizona についてご質問が ございましたら、ご希望の言語でサポートを受けたり、情報を入手したりすることができます。料金はか かりません。通訳とお話される場合、877-475-4799 までお電話ください。

Farsi:

اگر شما، یا کسی که شما به او کمک میکنید ، سوال در مورد Blue Cross Blue Shield of Arizona ، داشته باشید حتی این را دارید که کمک و اطلاعات به زبان خود را به طور رایگان دریافت نمایید 479-475-877 اتوان حاصل نماید

Assyrian:

1, نسمه، برسم فدوه و دموده من من من من من من من من من المنافعة على Blue Cross Blue Shield of Arizona؛ نسمه و مندم و مندم

Serbo-Croatian: Ukoliko Vi ili neko kome Vi pomažete ima pitanje o Blue Cross Blue Shield of Arizona, imate pravo da besplatno dobijete pomoć i informacije na Vašem jeziku. Da biste razgovarali sa prevodiocem, nazovite 877-475-4799.

Thai: หากคณ หรอคนทคณกาลงช่วยเหลอมคาถามเกยวกบ Blue Cross Blue Shield of Arizona คณมสทธทจะใดรบความช่วยเหลอและขอมลในภาษา ของคณไดโดยไม่มคาใช้จาย พดคยกบลาม โทร 877-475-4799